

INFORMED CONSENT LIPOSUCTION (waterbeam-assisted-liposuction, WAL)

INSTRUCTIONS This is an informed-consent document that has been prepared to help inform you concerning liposuction-surgery in WAL-technique, its risks, and alternative treatment.

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 surgeon.

INTRODUCTION Liposuction is a surgical technique to remove unwanted deposits of fat from specific areas of the body, including the face and neck, arms, trunk, abdomen, buttocks, hips and thighs, and the knees, calves, and ankles. This is not a substitute for weight reduction, but a method for removing localized deposits of fatty tissue that do not respond to diet or exercise. Liposuction may be performed as a primary procedure for body contouring or may be combined with other surgical techniques such as facelift, abdominoplasty, or thigh lift procedures to tighten loose skin and supporting structures.

The best candidates for liposuction are individuals of relatively normal weight who have excess fat in particular body areas. Having firm, elastic skin will result in a better final contour after liposuction. Hanging skin will not reshape itself to the new contours and may require additional surgical techniques to remove and tighten excess skin. Body-contour irregularities due to structures other than fat cannot be improved by this technique. Liposuction itself will not improve areas of dimpled skin known as "cellulite".

Liposuction-surgery is performed by using a hollow metal surgical instrument known as a cannula that is inserted through small skin incision(s) and is passed back and forth through the area of fatty deposit. The cannula is attached to a vacuum source, which provides the suction needed to remove the fatty tissue.

At first place a pulsed waterbeam ist used to bring in the anaesthetic fluid and also to wash out the fat tissue without damaging other structures like blood- and lymphatic-vessels.

There are a variety of different techniques used by plastic surgeons for liposuction and care following surgery. Liposuction may be performed under local or general anesthesia. Tumescent liposuction technique involves the infiltration of fluid containing dilute local anesthetic and epinephrine into areas of fatty deposits. This technique can reduce discomfort at the time of surgery, as well as reduce post-operative bruising.

Support garments and dressing are worn to control swelling and promote healing.

Risk of Liposuction, continued

ALTERNATIVE TREATMENT Alternative forms of management consist of not treating the areas of fatty deposits. Diet and exercise regimens may be of benefit in the overall reduction or excess body fat.

Direct removal of excess skin and fatty tissue may be necessary in addition to liposuction in some patients. Risks and potential complications are associated with alternative forms of treatment that involve surgery.

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

Patient selection – Individuals with poor skin tone, medical problems, obesity, or unrealistic expectations may not be candidates for liposuction.

Bleeding – It is possible, though unusual, to have a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or require a blood transfusion. Do not take any aspirin or anti-inflammatory medications for seven days before surgery, as this may increase the risk of bleeding.

Infection – An infection is quite unusual after this type of surgery. Should an infection occur, treatment including antibiotics or additional surgery may be necessary.

Skin scarring – Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. In rare cases, abnormal scars may result. Scars may be unattractive and of a different color than surrounding skin. Additional treatments, including surgery, may be needed to treat abnormal scarring.

Change in skin sensation – A temporary decrease in skin sensation after liposuction may occur. This usually resolves over a period of time. Diminished (or complete loss of skin sensation) infrequently occurs and may not totally resolve.

Skin discoloration/swelling – Skin discoloration and swelling normally occurs following liposuction. In rare situations, swelling and skin discoloration may persist for long periods of time. Permanent skin discoloration is rare.

Skin contour irregularities – Contour irregularities and depressions in the skin may occur after liposuction. Visible and palpable wrinkling of skin can occur. Additional treatments including surgery may be necessary to treat skin contour irregularities following liposuction.

Asymmetry – It may not be possible to achieve symmetrical body appearance from liposuction surgery. Factors such as skin tone, bony prominence, and muscle tone may contribute to normal asymmetry in body features.

Risk of Liposuction, continued

SEROMA – Fluid accumulations infrequently occur in areas where liposuction has been performed. Additional treatments or surgery to drain accumulations of fluid may be necessary.

LONG TERM EFFECTS – Subsequent alterations in body contour may occur as the result of aging, weight loss or gain, pregnancy, or other circumstances not related to liposuction.

TUMESCENT LIPOSUCTION – There is the possibility that large volumes of fluid containing dilute local anesthetic drugs and epinephrine that is injected into fatty deposits during surgery may contribute to fluid overload or systemic reaction to these medications. Additional treatment including hospitalization may be necessary.

Other – You may be disappointed with the results of surgery. Infrequently, it is necessary to perform additional surgery to improve your results.

Surgical anesthesia – Both local and general anesthesia involve risk. There is the possibility of complication, injury, and even death from all forms of surgical anesthesia or sedation.

Allergic reaction – In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur due to drugs used during surgery and prescription medicine. Allergic reactions may require additional treatment.

Surgical shock – In rare circumstances, liposuction can cause severe trauma, particularly when multiple or extensive areas are suctioned at one time. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. Should surgical shock occur after liposuction, hospitalization and additional treatment would be necessary.

Pulmonary complications – Fat embolism syndrome occurs when fat droplets are trapped in the lungs. This is a very rare and possibly fatal complication of liposuction. Should fat embolism or other pulmonary complications occur, additional treatment including hospitalization may be necessary.

Skin loss – Skin loss is very rare after liposuction. Additional treatments including surgery may be necessary.

Chronic pain – Chronic pain and discomfort following liposuction is very rare.

Risk of Liposuction, continued

HEALTH INSURANCE Most health insurance companies exclude coverage for cosmetic surgical operations such as liposuction or any complications that might occur from surgery. Please carefully review your health insurance subscriber-information pamphlet. Realize that there is a medical indication for liposuction on lipedema instead of a cosmetic motivated surgery. Because of that your health insurance should cover the treatment of complications.

ADDITIONAL SURGERY NECESSARY There are many variable conditions in addition to risk and potential surgical complication that may influence the long term result from liposuction. Even though risks and complications occur infrequently, the risks cited are particularly associated with liposuction. 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 The cost of surgery involves several charges for the services provided. The Total includes fees charged by your doctor, the cost of surgical supplies, laboratory test, anesthesia, and outpatient hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges no covered. Additional costs may occur should complications develop from the surgery. 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 surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). This documents is based on a through evaluation of scientific literature and relevant clinic practice to describe a range of generally acceptable risks and alternative forms of management of a particular disease or condition. 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 surgeon 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 of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve. This informed-consent document reflects the state of knowledge current at the time of publication.

Risk of Liposuction, continued

ADDITIONAL ADVISORIES:

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. Pulmonary complications may occur secondarily to 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. Air travel, inactivity and other conditions may increase the incidence of blood clots travelling 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 or swollen legs 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 heartbeats, seek medical attention immediately. Should any of these complications occur, you might require hospitalization and additional treatment.

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray): Patients who are currently smoking, use tobacco products, 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, smokers 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. Please indicate your current status regarding these items below:

_____ I am a non-smoker and do not use nicotine products. I understand the risk of second-hand smoke exposure causing surgical complications.

_____ I am a smoker or use tobacco/ nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired.

Female Patient Information: It is important to inform your surgeon if you use birth control pills, estrogen replacement, or if you believe you may be pregnant. Many medications including antibiotics may neutralize the 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. Increased activity that increased your pulse or heart rate may cause additional bruising, swelling and the need for return to surgery and control of bleeding. It is wise to refrain from sexual activity until your physician states it is safe.

Medications: There are many adverse reactions that occur as the result of taking over the counter, herbal, and/or prescription medications. 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 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. 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.

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 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 around implants and the need for the return to surgery. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

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

CONSENT FOR SURGERY / PROCEDURE OF TREATMENT

1. I hereby authorize Falk-Christian J. Heck, M.D. and such assistants as may be selected to Perform the following procedure or treatment:

I have received the following information sheet:
INFORMED CONSENT for LIPOSUCTION SURGERY

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 know 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 that may be removed.

8. I authorize the release of my identity card 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 OT TREATMENT PROPOSED
I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9).

I AM SATIFIED WITH THE EXPLANATION.

Patient or person Authorized to Sign for Patient

Date _____ Witness _____
Signature / Name