INFORMED CONSENT AUTHORIZATION TO PARTICIPATE IN A CLINICAL INVESTIGATION AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

Study Title:	**The Safety and Efficacy of Laser Assisted Liposuction and Facial Autologous Fat Grafting with the LipoLife™ System**
Protocol Number:	**ALM-Lipo-002**
Study Doctor:	**Jason Pozner, M.D.**
Site Address:	**Sanctuary Plastic Surgery 4800 N Federal Hwy, Boca Raton, Florida 33431**
Telephone Number:	**561-409-6230 (24 Hours)**
Sponsor:	**Alma Lasers Ltd.**

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

Research studies are voluntary and include only those who wish to participate.

INTRODUCTION

You are being asked to participate in this study because you are interested in undergoing lower abdominal liposuction (with or without flanks) and facial fat grafting.

The purpose of this document is to inform you in writing of the purposes of this study, a description of the procedures to be followed, possible risks and discomforts, possible benefits and the basic ground rules for this research study. When you have completed reading this form, and if you decide to participate, you may sign and date the form on the last page, initial and date each prior page, and return it to the study doctor's office. Please read this form carefully before you make your decision. You may refuse to participate in this study and this decision will not be held against you, nor will it change any matters between you and this office, and you will continue to receive the same medical care.

The study is being conducted for Alma Lasers Ltd. Your study doctor is being paid by Alma Lasers Ltd. to conduct this study.

Advarra Institutional Review Board (IRB) has reviewed the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

NATURE AND PURPOSE OF THE STUDY

Liposuction is routinely employed by plastic surgeons to remove excessive fat in various areas in the body. Liposuction has become the second-most commonly performed elective aesthetic procedure performed in the USA. The most commonly used liposuction techniques rely on mechanical, laser, ultrasonic or hydric forces. Laser assisted liposuction has been reported to be a safe and effective procedure.

Autologous fat grafting, a technique that involves implanting the patient's own harvested fat tissue from one body site to other body site, has become a popular filling material, particularly in the face and hands.

The LipoLife system, Alma Lasers' laser-assisted liposuction system, which will be used in this study, has been regulatorily approved, and is widely in use around the world.

The current study intended to collect data regarding laser assisted liposuction procedure with the LipoLife™ system, as well data regarding facial fat grafting with the harvested fat tissue.

STUDY DEVICE

The Alma Lasers Ltd LipoLife system, is cleared (approved) by the United States Food and Drug Administration (FDA) for laser assisted liposuction and fat grafting for aesthetic body contouring. Alma Lasers Ltd also has a CE mark for the LipoLife system, which means that the company can also sell this medical device also in Europe.

The use of the laser, while performing liposuction with the LipoLife system, enables softening of the connections between the fat cells and thus allows easier suction of fat cells compared with the mechanical technique, while maintaining patient safety. The use of the laser during liposuction may also lead to a tightening of the skin in the liposuction area. In addition, the fat collected through this system has high vitality and therefore suitable for autologous fat (taken from the study subject's own body body) grafting into various areas of the body, including the face.

In this study, the LipoLife system will be used to harvest fat tissue from the lower abdomen, with or without flanks. Some of the harvested fat will be injected into the face in order to improve facial aesthetic appearance.

STUDY OBJECTIVE

The purpose of this study is to evaluate the efficacy of Laser Assisted Liposuction procedure while using the LipoLife system (using before and after pictures, MRI and body weight measurements).

In addition the study is aimed to evaluate:

- The efficacy of facial fat grafting procedure using fat harvested with the LipoLife system (will be evaluated by comparing before and after pictures of the face and facial MRI)
- Subjects' satisfaction from the liposuction procedure and the facial fat grafting procedure (will be evaluated by subject satisfaction questionnaires)
- Procedure related adverse events

RESEARCH SUBJECT SELECTION

Up to twenty (20) volunteers will be enrolled in this research study, being conducted at two sites; Sanctuary Plastic Surgery Boca Raton FL, US (5 volunteers) and Yitzhak Shamir Medical Center, Israel (15 volunteers).

You are being invited to participate in this study because you have excessive fat in the lower abdomen (including or not including the flanks), and you are interested in undergoing lower abdominal liposuction (with or without flanks) and facial fat grafting for aesthetic improvement, and you meet all of the criteria to participate in this study.

It is important that you answer all of the screening questions completely. You must disclose all past and present diseases, allergies and all medications that you are taking, including prescription and nonprescription drugs. There may be reasons why you cannot participate in this study. The study doctor or study staff will discuss these with you.

<u>Photo release consent</u>

By signing this form you are allowing the sponsor (Alma lasers Ltd.) to use the photos taken during the study for educational and marketing purposes (your identity will be masked to the best possible extent in these pictures).

STUDY DESIGN AND DURATION

Your participation in this study is up to 8 months. If you agree to participate in this study, you will be required to make up to 6 visits. The first visit will be a screening visit in which the study doctor will determine if you can participate in the study. The second visit will include pre-surgery evaluation (a week before the surgery) and the third visit will be the surgery. Follow-up visits will be scheduled at 1, 3, and 6 months after the surgery.

STUDY PROCEDURES

Screening (Visit 1)

At the screening visit, you will be asked to sign and date this Informed Consent Form prior to any study procedures being performed. You will be asked for general information such as your age and weight. In addition, you will be asked to provide medical information such as medical history and medications used. A physical evaluation and vital signs assessment will be performed and you will be asked to perform a pregnancy urine test (if applicable) to rule out pregnancy. The study doctor will review whether you are eligible to participate in the study according to inclusion-exclusion criteria.

If you are eligible to the study, the study doctor may refer you to perform routine pre surgical evaluations, which may include: blood count, nasal swab test, E.K.G (a recording of the electrical signals of the heart for subjects more than 40 years old) and chest X-ray (for subjects more than 50 years old or with relevant background diseases) according to local institution regulation.

In addition the study doctor will refer you to perform an MRI (Magnetic Resonance Imaging) for abdominal fat thickness evaluation and facial fat volume assessment, prior to visit 2.

Pre-surgery evaluation (Visit 2)

The pre-surgery visit will take place a week before the surgery. At this visit the study doctor will assess your suitability to the surgery, according to pre surgery examinations results (if applicable), physical examination and reassessment of inclusion-exclusion criteria. You also may be referred to consult an anesthesiologist, who will give his/her approval to the surgery (optional, per local institutional regulation).

In addition, baseline study evaluations will be performed and will include body weight measurement, photography of designated liposuction area and photography of your face. You will be asked to bring your MRI results to this visit.

Surgery visit (Visit 3)

The study doctor will reevaluate your suitability to the study, according to inclusion-exclusion criteria, physical examination and vital sign assessment. In addition you will be asked to perform a pregnancy urine test (if applicable) to rule out pregnancy.

The surgery will include 3 stages;

1. Injection of local anesthesia
2. Laser assisted liposuction (harvesting fat tissue using the laser)
3. Facial fat grafting- Injection of some of the harvested fat tissue into the face

Follow up visits (Visit 4-6)
Follow up visits will take place 1, 3 and 6 months after the surgery.

During these visits, the study doctor will perform physical examination and vital sign assessment. You will be asked about adverse events (side effects) you may have experienced following the surgery and any change in medications. Study evaluations will be performed including body weight measurements, photography of the liposuction area and photography of your face. In addition you will be asked to fill out patient satisfaction questionnaires.

You will also be referred to perform additional MRI evaluations, just before visit 5.

Withdrawal Procedures
If you withdraw early from the study, for any reason, you will be asked to complete the discharge procedures as outlined in the Follow-up Visits section listed above.

Restrictions/Research Subject Responsibilities
As a research subject you will be asked to complete the study procedures for this study, come to the study clinic for all of your scheduled visits, follow the instructions listed in this informed consent form, and notify the study doctor if any information regarding your health or availability to participate in this study changes.

RISKS AND DISCOMFORTS
The procedures used in this study may cause all, some, or none of the listed risks/side effects. In addition, there is always the possibility of previously unknown or uncommon side effects.

- The possible risks of Laser assisted liposuction procedure may include:
    - local pain,
    - local hematoma (bruising),
    - contour deformities,
    - infection,
    - local scars or
    - systemic side effects such as electrolyte disorders.

- The possible risks of facial fat grafting procedure may include:
    - infection,
    - local hematoma,
    - fat necrosis (tissue death) or
    - injury of adjacent tissue.
    - Complications related to anesthesia and surgery

Blood collection risks: You may have pain or bruising at the site where the blood is drawn. You may feel faint. An infection at the site of the blood draw is possible.

ECG risks: You may have mild irritation, slight redness, or itching at the sites on your skin where the recording patches are placed.

MRI risks: There are very few risks known to be associated with MRI scans. The only risks relate to the presence of loose metalwork in the body (for example, surgical artery clips or foreign bodies) and patients with pacemakers.

UNKNOWN/UNFORESEEABLE RISKS
In addition to the risks listed above, there may be some unknown or infrequent and unforeseeable risks associated with the use of this study device. You will be informed in a timely manner both verbally and in writing of any new information, findings or changes to the way the research will be performed that might influence your willingness to continue your participation in this study.

RISKS TO THE UNBORN
***Pregnancy/Fetal Risks*:** The effects of the laser assisted liposuction procedure on an unborn child are unknown **and may be hazardous**.

If you think that you have become pregnant before the surgery or during the study, it is important that you inform the study doctor immediately. If you become pregnant or think that you may be pregnant, you will be removed from the study and the study doctor will refer you to seek obstetric care, the cost of which will be your responsibility. The study doctor may request to track your pregnancy and will report the pregnancy to the Sponsor and the IRB.

BENEFITS
After liposuction procedure, you may experience some reduction in your body circumference at the liposuction area. As a result from the facial fat grafting procedure, it is expected that the treated areas will receive some volume for a fresh and younger look. Response to these procedures is different for each individual, and we cannot and do not guarantee or promise that you will receive any benefits from this study.

COSTS
Office visits, examinations, and study procedures will be provided at no cost to you. There will be no costs to you other than for travel for your participation in this study.

PAYMENT
You will be paid $100 for each of the 3 and 6 months follow up visits. You will be paid a total of $200 at your last visit (6 month follow up visit). If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

TREATMENT ALTERNATIVE

- Alternatives treatments for liposuction includes dietary changes and physical training.
- There are several alternative techniques used for liposuction, including; mechanical, ultrasonic or hydric forces to harvest the fat.

  Mechanical liposuction may be faster than laser assisted liposuction. However, studies have shown that after mechanical liposuction, the patient is likely to have more local hematomas (bruising) at the treated area compared to laser assisted liposuction. There aren't any reported differences in the literature regarding laser assisted liposuction compared to ultrasonic or hydric forces liposuction.

The study doctor will discuss the risks and benefits of other treatments with you. While participating in this study, you should not take part in any other research project without approval from your study doctor.

RIGHT TO WITHDRAW OR REMOVAL FROM STUDY

You are free to withdraw from this study at any time, and you agree to inform the study doctor immediately if you intend to withdraw for any reason. To terminate your participation in this study, you must contact the study doctor at the contact information listed on page one of this informed consent form. You may be asked to come to the study clinic or study doctor's office to complete some end of study procedures. Your decision to participate in this study or to withdraw from this study will not influence the availability of your future medical care and will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw from this study at any time.

You agree that the study doctor in charge of the study can remove you from this study without your consent for any reason, including, but not limited to:

a. His/her judgment that any condition or circumstance may jeopardize your welfare such as increased risk, change in potential benefit, or the integrity of the study.
b. Your failure to follow the instructions of the study doctor(s).
c. If the study is stopped by the sponsor and/or doctors participating in the study prior to completion.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00028811.

CONFIDENTIALITY AND AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

This study can be performed only by collecting and using your personal health information. Your study records will be kept as confidential as possible under local, state and federal laws. Personnel from the following organizations may examine your study records: the sponsor, Alma Lasers Ltd., personnel associated with this study (including monitors and auditors), the IRB, and regulatory agencies, such as the United States Food and Drug Administration (FDA). Because of the number of individuals who may see your records, absolute confidentiality cannot be guaranteed.

Personal health information that may be used and disclosed includes that which is obtained to determine your eligibility to participate and that which is collected from the procedures that are carried out. It may identify you by name, address, telephone number, Social Security Number, study number, date of birth or other identifiers. Once the information is disclosed, it is possible that it may be re-disclosed, at which time it may no longer be protected by federal regulations, but may be by state laws. If the final study data are prepared for publication and other reports, your identity will not be revealed. Under these federal privacy regulations, you have the right to see and copy any of the information gathered about you, until your study records are no longer kept by the study doctor. However, it may not be available until the study has been completed.

You may, by written notice to the study doctor at the address listed on the first page of this form, cancel your authorization to use or disclose your personal information at any time. If you withdraw your authorization, the information collected up to that time may still be used to preserve the scientific integrity of the study. By signing this consent form, you authorize these uses and disclosures of your personal information. If you do not authorize these uses

and disclosures, you will not be able to participate in the study. This authorization does not have an expiration date.

IN CASE OF INJURY

If a research-related injury occurs, the Sponsor, Alma Lasers Ltd. will pay for any treatment of research-related injury to the extent that such costs are not covered by your health insurance policy. However, the Sponsor will not pay for pre-existing conditions or for any conditions unrelated to the study treatment. You must follow the instructions of the study doctor to be eligible for this coverage. Also, the Sponsor has no plans to compensate you for wages associated for lost-time at your work place or dissatisfaction with treatment outcome.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing this consent document.

If you are injured during this study, your study doctor will discuss with you the available medical treatment options.

By signing this form you **have not** given up any of your legal rights.

POSTING OF RESEARCH STUDY ON WEB

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT STATEMENT

I have read in a language I understand well the above description of this research study. I have been informed of the risks and benefits, and all my questions have been answered to my satisfaction. By signing this form, I voluntarily consent to participate in the research study and authorize the release of my personal health information.

I authorize the use and disclosure of my personal health information for the purposes of this study. Refusal to give my authorization means I cannot participate, but my future medical care will not be affected.

I voluntarily agree to participate in this study. I will be given a copy of this signed and dated form.

_____ _____
Research Subject's Name (printed) Research Subject's Age

_____ _____
Research Subject's Signature Date/Time

_____
Study Doctor's/Study Staff's Name (printed)

_____ _____
Study Doctor's/Study Staff's Signature Date

Copy of signed and dated consent form given to the research subject on (date) _____ by (initials) _____