



ZERONA Low Level Laser Therapy Consent Form

A. Program and Background

You have requested to be treated with the ZERONA low-level laser therapy manufactured by Erchonia Medical. This treatment is the application of a 635nm low intensity laser, which has been shown through extensive research to cause the fat within the adipocyte (fat cell) to leave the cell and accumulate in the interstitial space around the cells. In contrast to high-power, high heat lasers that are used in various medical procedures, the low level laser used for this treatment has no thermal effect on tissue. Instead, the non-invasive laser helps the body absorb fat by stimulating its biological function. Excess fat is then removed naturally by the body's lymphatic system and subsequently excreted without the negative side effects and downtime associated with more invasive procedures such as liposuction. This therapy has been tested in several institutional review board approved studies in a double blind; placebo controlled fashion and found to be generally effective. Any medical or cosmetic procedure carries risk, complications and varied results as to the effectiveness of a particular treatment. The purpose of this document is to make you aware of the nature of this product and its risks in advance so that you can decide whether to go forward with this procedure.

The ZERONA is the first non-invasive aesthetic device to receive FDA market clearance in the U.S. for circumferential reduction of the waist, hips, and thighs.

B. Procedure

Initially you will consult with the doctor to determine if you are a candidate for low level laser therapy. During this time period you will have the opportunity to ask questions or voice concerns you may have concerning this treatment. If it is determined you are a candidate for this procedure, there will be a few preliminary steps consisting of paperwork, measurements and photos. Proceeding, the patient will need to undress to their undergarments and will lie down. From here the treatment will be administered by aiming the ZERONA five 635nm low level laser heads on the desired areas to be treated. There are some other options available to patients; however for body contouring the patient will be treated for twenty minutes on the front of the desired area to be treated. Once this initial twenty minute period has expired, the patient will then turn over and the back of the desired area will be treated for another twenty minutes. It is recommended that a patient will need a minimum of six treatments for the low level laser to achieve its potential effect.

This treatment should be used in conjunction with a healthy diet, exercise and the Niacin (Vitamin B3). If you are not currently exercising you should consult a health care professional before beginning an exercise program to determine if your body is physically able. The use of Niacin (Vitamin B3) is recommended in conjunction with this treatment. The doctor will review your medical history to determine if the use of Niacin is right for you. Niacin is used to assist your body in removing fat from your blood stream. Niacin has been know to reduce LDL cholesterol, reduce triglycerides and increase HDL cholesterol.



C. Risks/Discomfort

There are a few risks associated with low-level laser therapy. This treatment is non-invasive and uses a cold output laser. During treatment no discomfort will be present, the patient will not feel the laser, however the light will be visible. The only discomfort that may occur is if a patient is taking Niacin. Niacin is a vasodilator, and a naturally occurring flush can cause the upper extremities, face, neck and ears to become red and itch. The only known or anticipated risk with the use of the laser device is that long-term exposure to laser light could cause damage to your eyesight. You will be provided with protective eyewear and to avoid this risk, you must wear them throughout the course of your treatment.

*** Please inform us if you think you are pregnant, or are unsure if you may be pregnant, as a pregnancy test may be required to proceed with treatment. Although no known detrimental risks exist, potential unknown risks may exist.**

If you have a pacemaker, this treatment may not be right for you. It is recommended that one does not treat directly over a pacemaker or its lead wires. No known risks exist, however potential unknown risks may exist.

It is possible that you may not see any improvement in your body shape or it may get worse. There also maybe the unknown risks associated with low-level laser therapy.

D. Benefits

Over the years, the benefits of low-level laser therapy have become more prominent. Low-level laser therapy has been used by chiropractors for pain management and recently by cosmetic surgeons to emulsify adipose tissue before liposuction with FDA approval. The potential benefit of this treatment is body contouring without surgery. Problem areas or excess pockets of fat can be targeted, however the most commonly treated areas are the stomach, hips and thighs. These results do vary and no guarantee is implied or suggested that desired results will be achieved.

E. Alternatives

This is a strictly voluntary cosmetic procedure. No treatment is necessary or required. Alternative treatments, which vary in sensitivity, effect, duration, and invasiveness include: liposuction, mesotherapy, lipodissolve, velasmooth, dieting, exercise and potential others; which may have their own risks and benefits. You acknowledge this, and realize that the other option for you is do nothing.

F. Questions

By signing below, you certify that this procedure has been explained to you to your satisfaction. Any further questions can be directed to Dr. Karen Tedeschi, Tedeschi Wellness Center.



H. Consent

I have reviewed this consent form. My consent and authorization for this procedure is strictly voluntary. By signing the informed consent form I grant authority for Tedeschi Wellness to perform the described treatment or administer any related treatment as deemed necessary or advisable for my medical condition.

The purpose of this procedure, risks, complications and alternative methods of treatment have been fully explained to my satisfaction. No guarantee has been given by anyone as to the results that may be obtained by this treatment.

I have read this informed consent and certify that I understand its contents in full. I have had enough time to consider the information and feel I am sufficiently advised to consent to this procedure. I hereby give my consent to have this procedure.

PHYSICIAN ATTESTATION

I have explained the procedure, alternatives and risks to the person or persons whose signature is affixed below. The patient has verbally communicated to me that they understand the contents of this form.

Signature of Physician

Date

PATIENT CERTIFICATION

By signing below I state that I am 18 years of age or older, or otherwise have authorized to consent. I have read or have had explained to me the contents of this form. I understand the information on this form and give my consent to what has been explained to me.

Signature of Patient

Date

INTERPRETER ATTESTATION (When applicable) I have provided translation to the person(s) whose signature(s) are affixed above.

Signature

Date