



# ZERONA™ Low Level Laser Consent and Release Form

Name: \_\_\_\_\_

## 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 advanced so that you can decide whether to go forward with this procedure. Non-invasive low level laser therapy has been approved by the FDA.

## 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 change into a hospital gown and will lie down. From here the treatment will be administered by aiming the Zerona's five 635nm low level laser heads on the desired area(s) 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 use of 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 the fat from your blood stream. Niacin has been known to reduce LDL- cholesterol, reduce triglycerides, and increase HDL- cholesterol.

## C. Risks/Discomfort

There are 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 eyesight. You will be provided with protective eyewear and to avoid this risk, you must wear them throughout the course of your treatment. The only discomfort that may occur is if a patient is taking Niacin. Niacin is a vasodilator, Niacin (Vitamin B3) which will cause a "flush" reaction on your skin. This typically occurs 15-30 minutes after application and lasts about 30 minutes.

The experience can be uncomfortable: red, hot and itching skin; **this reaction is expected, normal and very helpful in eliminating the liquefied fat.**

Niacin should be avoided for people who have liver problems, diabetes, ulcers, gout, or taking high blood pressure medications.

Tell the Doctor if you are concerned about this supplement.

**\*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. There are also a variety of other conditions for this treatment. It is possible that you may not see any improvement in your body shape or it may get worse.

There also may be 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 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, flanks, and thighs. In clinical trials patients have averaged 4.5 inches lost from there 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 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 there own risks and benefits. You acknowledge this, and realize that the other option to you is do nothing.

#### **F. Questions**

By signing below, you certify that this procedure has been explained to you and your satisfaction. Any further questions can be directed to Reveal Zerona.

#### **G. Consent**

I have reviewed this consent form. My consent and authorization for this procedure are strictly voluntary. By signing the informed consent form I grant authority for Reveal Zerona 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, alternative methods of treatment have been fully explained to my satisfaction. I understand the distinction between "on label" and "off label" use of Erchonia's Zerona low-level laser therapy.

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 herby give my consent to have this procedure.

If at any time during the Zerona procedure I experience pain or discomfort of any kind, I agree to inform the staff immediately and/ or terminate the session at my discretion.

The undersigned assumes all responsibility for behavior of self and their clients and agrees to abide by all Rules and Procedures of the property.

Clients are responsible for the completion and timely return of any client forms and payments, including but not limited to new client intake forms scheduling.

The clients and all persons on the premises by invitation of the clients herby hold Reveal Zerona, its employees, the corporation or any individual connected in any way to Reveal Zerona, harmless for any responsibility or liability for

any accident, injury illness or damages sustained by or to any person or their personal property during their treatment appointments or use of facilities. Reveal Zerona shall be indemnified and held harmless by the clients, and clients agree to pay all costs incurred in connection with any accident, injury illness or property damage loss, including attorney's fees, regardless of how it may have occurred.

The undersigned hereby releases and indemnifies Reveal Zerona and holds harmless any employee, the corporation or any individual connected in any way to Reveal Zerona for any loss of personal property and/ or accident causing personal injury of any nature, including reasonable attorney's fees and court costs in connection therewith.

However, in the event of an occurrence, the client should inform our team members who will do everything within reason to rectify the problem.

All information regarding the procedure is checked to ensure the accuracy of descriptions. However, we are not always able to control all of the components of the facility, city power outages, etc., and it is possible that an appointment time or procedure may become unavailable due to circumstances beyond our control and for which we do not accept liability.

I further state that I am of lawful age and legally competent to sign this aforementioned release; I understand the terms herein is contractual and not a mere recital; I have signed this document of my own free act.

At Reveal Zerona we place the highest priority on the client's right to privacy. We recognize the added sensitivities for client's receiving body sculpting therapy. Our office staff is trained to protect our private health information, and our waiting areas are intentionally shielded and discrete.

We value your privacy, and are committed to maintaining your security and confidentiality in the use of any information you choose to share with us. **We do not disclose identifiable information to any third party without your consent.** Further, **we do not sell, rent, or otherwise allow the unauthorized outside use of personal information such as names, addresses, phone numbers, or e-mail addresses in our database without your permission.**

**Nevada residents :** Reveal Zerona is an independent contractor and is in no way associated with Horizon Ridge Wellness Clinic and hereby releases and indemnifies Horizon Ridge Wellness Clinic and hold harmless any employee connected in any way to Horizon Ridge Wellness Clinic for any loss or personal property an or accident causing personal injury, including reasonable attorney's fees or court cost in connection therewith.

**Copies of this form and signature will be valid as if original if this document is digitally scanned.**

**PHYSICIAN and or LASER TECH ESTHETICIAN**

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 the above information. I have read or have had explained to me the contents of this form. I understand that information on this form and give my consent to what has been explained to me.

**I HAVE ALSO RECEIVED A COPY OF THE POLICY AND PROCEDURE'S**

\_\_\_\_\_  
Signature of Patient

\_\_\_\_\_  
Date