

### ZERONA® Low Level Laser Treatment Consent

You have requested to be treated with ZERONA®, a low-level laser manufactured by Erchonia Medical®. This treatment involves the application of a 635nm low intensity laser, which has been shown through extensive research to break down the fat cell membrane in the areas being treated, stimulating the body to rid itself of the excess fat. Excess fat is then removed naturally by the body's lymphatic system and subsequently excreted without the potential side effects and downtime associated with more invasive procedures such as liposuction. In contrast to high-power, high heat lasers that are used in various medical procedures, the low level laser used for this treatment is a "cold" laser and has no thermal effect on tissue. ZERONA® therapy has been tested in several institutional review board approved studies and was found to be generally effective in measurably reducing body contours. Though safe and non-invasive, any medical or cosmetic procedure carries risks, complications and varied results as to its effectiveness. 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.

Non-invasive low level laser therapy has been approved by the FDA when used in conjunction with liposuction. \_\_\_\_\_ has been using the Erchonia® low level laser safely and effectively in this manner in conjunction with liposuction surgery since \_\_\_\_\_. The ZERONA® low-level laser treatment, when used without liposuction, is currently considered an "off label" use of this device. The data from these studies, though convincing, is pending FDA approval.

If there are no contraindications, the use of CURVA™ may be recommended in conjunction with this treatment, as it has been shown to greatly enhance the results by assisting your body in removing the fat from your blood stream. Niacin, a component in CURVA™ has been shown to lower serum LDL-cholesterol and triglycerides as well. \_\_\_\_\_ will review your medical history to determine if the use of CURVA™ is right for you. **Note** that because CURVA™ contains niacin, a vasodilator, you may experience flushing or itching of the upper extremities, face, neck, or ears.

During ZERONA® treatments there will be no discomfort and you will not feel the laser. However, the light will be visible. There are few risks associated with low-level laser therapy. The only known risk with the use of this device is that long-term exposure to laser light may cause damage to your eyes if unprotected. *You will be provided with protective eyewear during your procedure and you must wear them throughout your treatment to avoid this risk.* It is possible that you may not see any improvement in your body contour. In addition, there may be unknown risks associated with low-level laser therapy of which we are not yet aware. Current alternative treatments, which may vary in effectiveness, include, but are not limited to: liposuction, mesotherapy, lipodissolve, dieting and exercise, or do nothing at all. These alternatives may have their own risks and benefits. ZERONA® Laser Liposculpture works by reducing the fat content of your fat cells in the area treated, not by removing fat cells (The only way to permanently remove fat cells is by liposuction surgery). Eating poorly, not exercising properly and gaining weight will likely reverse the results of your treatment as the fat may re-accumulate in your fat cells.

I understand this is an elective, cosmetic procedure and that the prescribed series of treatments is required to achieve desired results. I understand the practice of medicine and surgery is not an exact science and I acknowledge that no guarantees have been made to me concerning the results of this procedure. I understand that I must follow the pre and post treatment regimen as prescribed by \_\_\_\_\_ and staff, including:

**PATIENT RESPONSIBILITIES**

**PATIENT INITIAL**

- Staying hydrated -- (drink at least 64 oz each day) \_\_\_\_\_
- Take CURVA™ therapy (if indicated) \_\_\_\_\_
- Eliminate consumption of alcohol \_\_\_\_\_
- Adhere to proper diet \_\_\_\_\_
- Exercise as outlined in the Patient Procedure Guide \_\_\_\_\_

Failure to follow the outlined Patient Protocol may result in failure to achieve the desired results. Complications or a poor outcome may manifest weeks, months, or even years after the ZERONA® laser treatment. In addition, I am not now, and do not expect to become pregnant during the course of my ZERONA® treatment. Although there is no known detriment to low level laser treatment during pregnancy, potential unknown risks may exist.

\_\_\_\_\_ and staff have explained ZERONA® low level laser and its risks, benefits and alternatives, including not doing the procedure, and have answered all my questions about this procedure. I therefore consent to having ZERONA® low-level laser treatments.

\_\_\_\_\_  
 Patient Name – print

\_\_\_\_\_  
 Witness Name - print

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

\_\_\_\_\_  
 Date

\_\_\_\_\_  
 Witness Signature

\_\_\_\_\_  
 Date

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