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VERJU™ Low Level Laser Therapy Consent Form

You have requested to be treated with the VERJU laser therapy manufactured by Erchonia Medical®. It is a new non-invasive body slimming and appearance of cellulite procedure designed to remove fat, slim the body without surgery, pain, or needles. VERJU works in two ways using a patented and clinically proven low level laser technology. VERJU emulsifies fat within the adipose tissue which is then released into the interstitial space. The excess fat is then passed through the body during its normal course of detoxification. In addition, the VERJU softens the connective tissue. These are the two main causes of cellulite.

This treatment is the application of a 532nm 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, randomized, multi-site, 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.

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, lab work and photos. For your convenience, you will be given the option of choosing the frequency of your visit:

- Once a week for six weeks consecutively
- Twice a week for three weeks consecutively
- Three times a week for two weeks consecutively

The doctor will recommend the appropriate length of laser treatment:

- 15 minutes
- 30 minutes
- 40 minutes

Jewelry should be removed if it is located in the treatment area to avoid any reflection for the laser light. You are required to bring your own non-constrictive black undergarments; these will not be provided to you. For the sake of consistency, please wear these same undergarments for each photo session (1st Visit, 6th Visit, and the 7th Visit).

Prior to treatment, the patient must arrive for the treatment with clean, dry skin.

The treatment will be administered by aiming the VERJU'S six 532nm low level laser heads on the desired area(s) to be treated. For the first half of the treatment, the patient will be treated on the front of the desired area to be treated. The patient will then be turned over and the back of the desired area will be treated for the remaining period. 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 our low carbohydrate, modified Mediterranean diet, moderate exercise (20-minute walking), and specified daily water intake, prescribed vitamins / supplements, and a protein powder. It is also highly suggested that the patient wears a compression garment daily that covers the treated areas to maximize the effect of laser treatment. Alcohol consumption, coffee, and the use of diuretics must be minimized.

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 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.

Contraindications

- **Pregnancy - 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. The Practitioner may ask for a urine sample to test for pregnancy prior to initiation of treatment.
- Pacemaker - if you have a pacemaker and /or AICD (Automatic Implantable Cardio-Defibrillator), 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.
- Active Cancerous Tissue (active cancer cells)
- Active Injections or compromised immune system (chronic, progressive, immuno-logical condition that requires medical intervention) – i.e. HIV / AIDS
- Photosensitizing drugs (currently prescribed a photo-sensitizing agent - i.e. Accutane and antibiotics)
- Prescribed anti-coagulants (i.e. Coumadin, Plavix, Warfarin, Xarelto)
- Open wound at site of treatment.

Cautionary Conditions

There are specific conditions or medications that may affect the metabolic rate or enervate the fat mobilization or metabolism pathway. Accordingly, a decision to wait for condition stabilization prior to treatment must be evaluated for the following conditions / medications:

- Steroid medication (may cause weight or girth gain)
- Uncontrolled Diabetes (may experience rapid weight or girth gain)
- Metabolic Disorders such as Hypothyroidism or non-stable Thyroiditis (may experience rapid weight or girth gain)
- Lymphatic Impairment (fat mobilization may be hindered)
 - Previous abdominoplasty, C-section, liposuction, other abdominal procedures, and other surgeries that have created scar tissue around the treatment site

The decision to treat a patient rest solely with the VERJU Practitioner (Dr. Eileen Comia).

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.

Benefits

Over the years the benefits of low-level laser therapy have become more recognized. 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.

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, lipo-dissolve, vela-smooth, dieting, exercise and potential others; which may have their own risks and benefits. You acknowledge this, and realize that the other option to you is do nothing.

Questions

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

VERJU COLD LASER THERAPY INFORMED CONSENT

I have reviewed this consent form. My consent and authorization for this procedure are strictly voluntary. By signing this consent form, I grant authority to Dr. Comia and her staff to perform the described treatment or administer any related treatment as deemed necessary or advisable for my medical condition. I will not hold liable Dr. Eileen C. Comia, Advance Biomedical Treatment Center, any of her staff or any other person associated with the treatment. I fully understand the risks for doing the cold laser treatments.

The purpose of this procedure, its risks, its complications, alternative methods of treatment, has 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.

PATIENT CERTIFICATION

By signing below, I state that I am at least 18 years of age and am authorized to consent. I have read and fully understand the information provided to me. I hereby give my consent to have this procedure.

Printed Name

Date of Birth

Signature

Date

PHYSICIAN ATTESTATION

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

Signature of Physician

Date