UWave For Erectile Dysfunction | Patient Consent Form

Men's Health Center Clinic: (317) 564-5104

This document is intended as confirmation of informed consent for UWave™ therapy, also known as Low Intensity Shockwave Therapy (LIST) as ordered by your provider. Please watch the following patient education video in its entirety prior to reading and signing the following consent form. https://bit.ly/3iOTPN0

If you have further questions about LIST therapy after watching the provided educational video and reading the following consent and wish to discuss the issue further, please call (317) 564-5104 and request a consultation with a member of our Men's Health Center team. This may be completed in person or via TeleHealth.

A. PURPOSE

LIST therapy is a non-invasive therapeutic technique that uses pulsed acoustic sound waves to promote blood flow to the treated area. LIST therapy is generally considered to be safe and is used for a variety of health conditions.

When a medical device is approved for use by the Food and Drug Administration (FDA), the device manufacturer produces a "label" to explain its use. Once a device is approved by the FDA, physicians may use it "off-label" for other purposes if they are well-informed about the device, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects.

The LIST device used in the therapy is cleared by the FDA for intended use as a treatment for plantar fasciitis.

The LIST device is being used in the therapy as an "off-label" use. This usage is based upon scientifically designed, international clinical studies that have shown LIST to be effective in optimizing sexual health and wellness, including erectile dysfunction. As an off-label treatment, LIST for erectile dysfunction is not covered by insurance and full payment of **$1500 USD** for an entire treatment course is required prior to initiating therapy.

B: BENEFITS

Scientific studies have shown that when applied to an area, LIST increases blood flow, by stimulating the growth of new blood vessels (neovascularization) and growth factors thus enhancing tissue growth and repair.

C. CONSENT FOR PROCEDURE

I have received either written or verbal information about my condition, the proposed treatment, alternatives, and related risks. I have received an explanation of any unfamiliar terms and have been offered the opportunity to ask questions. This form contains a brief summary of this information. I understand I may refuse consent and I GIVE MY INFORMED AND VOLUNTARY CONSENT to the proposed procedures and the other matters shown below. I also consent to the performance of any additional procedures determined in the course of a procedure to be in my best interests and where delay might impair my health.

1. I authorize Practitioner to treat my condition, including performing further diagnosis, the therapy procedures described below, and such photographs as may be recommended for medical records only. I acknowledge that my treatments will be performed by trained staff who have demonstrated repeated proficiency in the application of LIST therapy.

2. I understand the purpose of the therapy procedure(s) to be: apply Low Intensity Shockwave Therapy with an FDA cleared medical device to those areas that the Practitioners believes will be most effective in optimizing sexual health.

3. Although LIST has been performed on thousands of patients and the risks are very low, we must list them. I understand the most common risks associated with the proposed procedure(s) to be: swelling, reddening of skin, soreness. Less common risks to the proposed procedure(s) to be: hematoma (bruising), petechiae (minor broken blood vessels). Although unlikely, I acknowledge that there may be a theoretical risk of the development of Peyronie's disease or other scar tissue in response to LIST therapy.

4. I also understand that there may be other RISKS OR COMPLICATIONS, OR SERIOUS INJURY from both known and unknown causes. I am aware that the practice of medicine and surgery is not an exact science and I acknowledge that no guarantees have been made to me concerning the risks of the procedure.

5. By initiating a course LIST, Practitioner is using his or her best judgment in recommendations for you and there is no guarantee of an outcome.

6. I understand that if I did not wish to accept the risks associated with this therapy then I would choose to not sign this consent.

7. I have informed the Practitioner of any known allergies to drugs or other substances, or of any past reactions to anesthetics. I have informed the Practitioner of all current medications and supplements I am taking.

8. I understand that my full treatment course will consist of 6 treatments spread out over approximately 3 weeks and that compliance with these appointments is essential to maximize my chances for success.

D. PATIENT CERTIFICATION

By signing below, I state that I have watched the provided patient education video in its entirety. I affirm that I have fully comprehended its contents in addition to the information provided in this consent form. I affirm that I have had the opportunity to have all my questions regarding LIST therapy answered to my satisfaction. I acknowledge that I have been given the opportunity for pre-procedure appointment with the Men's Health Center team should I desire further consultation.

Name (print): _____

Signature: _____

Date: _____

By signing below, I state that I am 18 years of age or older, or otherwise 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 is described above and to what has been explained to me.

Name (print): _____

Signature: _____

Date: _____