LISWT Patient Consent

This document is intended as confirmation of informed consent for Low Intensity Shockwave Therapy (LISWT) as ordered by your provider. If you have further questions about LISTW therapy after reading the following consent and wish to discuss the issue further, please follow up with your referring provider or request a consultation with a member of our Men's Health Center team. This may be completed in person or via TeleHealth.

A. PURPOSE

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

The use of the LISWT device in optimizing sexual health, including erectile dysfunction, is an "off-label" use. 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 LISWT device used in the therapy is cleared by the FDA for intended use as a treatment for plantar fasciitis. The "off label" usage of LISWT for men's sexual health is based upon scientifically designed, international clinical studies that have shown LISWT to be effective.

As an "off-label" treatment, LISWT for erectile dysfunction is not covered by insurance and full payment of $1800 USD for an entire treatment course (6 treatments) is required prior to initiating therapy.

B: BENEFITS

Scientific studies have shown that when applied to an area, LISWT 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 and associates at Urology of St. Louis to treat with the therapy: Low Intensity Shockwave Therapy with an FDA cleared medical device applied to those areas that the Practitioner believes will be most effective in optimizing sexual health.

2. Although LISWT 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) are: 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 LISWT therapy.

3. 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.

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

5. 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.

6. 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.

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

D. PATIENT CERTIFICATION

By signing below, I affirm that I have had the opportunity to have all my questions regarding LISWT therapy answered to my satisfaction. 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: _____