Patient Consent For GainsWave Therapy

This document is intended to serve as confirmation of informed consent for GAINSWave™ Therapy, also known as Extracorporeal Shock Wave Therapy (ESWT), as ordered by your medical practitioner (Practitioner).

A. PURPOSE

ESWT therapy is a non-invasive technique that uses pulsatile waves to stimulate blood flow to the applied area. ESWT is a safe procedure and has been 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 ESWT device used in the therapy is cleared by the FDA for intended use as a treatment for minor aches and pains and for the temporary increase in local blood circulation.

The ESWT 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 ESWT to be effective in optimizing sexual health and wellness, including erectile dysfunction.

B: BENEFITS

Scientific studies have shown that when applied to an area, ESWT 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.

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

3. Although ESWT 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).

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 ESWT, 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.

D. CONSENT FOR LOCAL ANESTHESIA

When local anesthesia and/or sedation is used by the practitioner. I consent to the administration of such local anesthetics as may be considered necessary by the practitioner in charge of my care. I understand that the risks of local anesthesia include: local discomfort, swelling, bruising, allergic reactions to medications, and seizures from lidocaine.

E. PATIENT CERTIFICATION

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.

_____/_____SIGNATURE OF PATIENT and DATE