สยามคลินิก
SIAM CLINIC

Patient Consent for Shockwave Therapy for Erectile Dysfunction

This document is intended to serve as confirmation of informed consent for Shockwave Therapy for Erectile Dysfunction, chronic tendon inflammation in the hip, knee, shoulder, elbow, Achilles and sole of the foot. It is recommended for conditions such as heel pain (plantar fasciitis), tennis or golfers' elbow, tendinitis of the shoulder, tendinopathies of the Achilles tendon, hamstring and patella, as well as other painful conditions such as trochanteric bursitis and shin splints., 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.

Are there contraindications and/or precautions? Contraindications include:

- Coagulation disorders, thrombosis, heart or circulatory patients
- Use of anticoagulants, especially Heparin, Coumadin
- Tumor diseases, carcinoma, cancer patients
- Pregnancy
- Polyneuropathy in case of diabetes mellitus
- Acute inflammations/pus focal in the target area
- Children in growth, open growth plates
- Cortisone therapy within the last 6-12 weeks

Side effects include: (These side effects generally abate after 5-10 days).

- Swelling, reddening, hematomas
- Petechiae, bruising
- Pain
- Skin lesions (especially after previous cortisone therapy)