Patient Consent For SoftWave Therapy

This document is intended to serve as confirmation of informed consent for SoftWave therapy, also known as Extracorporeal Shock Wave Therapy (ESWT), as recommended 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 this therapy is FDA 510(K) cleared for the activation of connective tissue and registered for pain reduction and improved blood supply.

B: BENEFITS
Scientific studies have shown that when applied to an area, ESWT increases blood flow and activates connective tissue while relieving pain and inflammation.

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, and the therapy procedures described below.

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 Practitioner believes will be most effective in treating my condition.

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.

D. 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

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DATE

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