



## **Consent Form for Treatment Women's Health Division**

I acknowledge and understand that I am consenting to an occupational therapist at FIG Wellness Therapy: Women's Health Division for an evaluation and treatment related to my condition. FIG Wellness Therapy addresses various conditions, and the therapist will position the applicator to contact the targeted treatment areas externally directly. This treatment does not involve drug administration or internal pelvic evaluation/treatment.

I understand that I will be given the opportunity to provide or revoke my consent at each step during the treatment session. Verbal consent will be continuously obtained throughout each session. I retain control over my body and any actions performed during sessions, including Softwave therapy. For further patient education, I may contact Kun-Yen Kuo, the Owner of the Women's Health Division, at (602) 887-7632.

By signing the consent section on our Client Intake Form, I acknowledge, understand, and accept all the explanations in the consent form and consent to have this therapy administered.

### **Treatment Process**

The treatment sessions usually take approximately 20 minutes, with Softwave treatment taking an average of 15 minutes. First, the gel is applied to the area that needs treatment. Then, the therapist uses an applicator that produces deep acoustic wave pulses to the targeted tissues. The applicator stays in these areas until the pulses deliver adequate healing energy for each session.

These sound waves penetrate deep into damaged tissue. Additionally, electrohydraulic shockwaves have proven to increase small, medium, and large blood vessels by 300% within 12 weeks following the first treatment.

For Softwave treatment, the therapist will NOT insert a gloved finger(s) into the perineal region, including the vagina and/or rectum, as in conventional Pelvic Floor Therapy. Treatments require observing and positioning the applicator to contact the targeted areas directly.

## Clothing and Modesty

You will need to remove specific clothing items, such as a bra for mastitis or underwear for pelvic conditions, to allow the therapist access to the necessary treatment areas. The therapist will provide disposable drapes to maintain my modesty and comfort throughout the procedure.

\*\*To enhance the delivery of healing energy to the tissue, please consider removing excessive hair from the targeted areas.

## Potential Risks

Softwave triggers natural healing by modulating inflammation to release Exosomes, promoting cell repair. Most patients feel good after treatments without issues. However, Softwave treatment may temporarily increase the current level of pain, discomfort, or itchiness. If discomfort persists beyond 1-3 days, you will contact Kun-Yen Kuo, the owner.

After receiving shockwave therapy, you may experience fatigue for 24 to 48 hours. This is a natural reaction of your body's cells repairing and healing themselves. These therapies stimulate the healing process, and your body works hard to heal and improve. Proper hydration is critical in the process.

Softwave Tissue Regenerative Technology functions uniquely compared to other shockwave devices. While certain shockwave devices can pose risks to internal organs, Softwave—known as Sparkwave in Europe, where it was designed with safety as a top priority—avoids such dangers. This safety focus makes Softwave particularly beneficial for treating women's health conditions, including pelvic health issues and mastitis.

## Potential Benefits

Softwave treatment enhances quality of life by alleviating pain, reducing inflammation, promoting tissue healing, stimulating natural stem cells for healing without medications, and improving functions.

While Softwave Therapy provides significant benefits, it's essential to understand it's not a miracle cure. For a detailed list of conditions we treat, please visit our website. If your specific condition isn't listed, we encourage you to contact FIG Wellness Therapy to discuss the potential benefits of Softwave therapy for you. Please note that while we offer treatment for various Women's Health-related conditions, there are conditions we may not address. FIG Wellness Therapy strictly adheres to regulations and operates within the scope of practice for Occupational Therapy in Women's Health.

## What is “Softwave Therapy”?

Softwave is the only device in the Shockwave family that does not induce micro-trauma, trigger the body's stem cells to activate a healing reaction, and has no adverse side effects. These benefits make Softwave a unique form of technology in the Shockwave family of devices.

Shockwaves are acoustic pulses that apply short, frequent, and high- intensity bursts of mechanical energy (in the form of a shockwave) into soft tissue that is injured, scarred, contains adhesions, is painful, or inflamed.

Shockwave is not ultrasound. It is in its category because it can reach deeper tissues and stimulate stem cells. Unlike ultrasound, it does not cause heat to build up in the tissues.

## How is Softwave Regenerative Technology different from other shockwave devices?

Softwave Tissue Regenerative Technology is uniquely designed to utilize focused and unfocused shockwaves. This cutting-edge feature allows Softwave to provide a comprehensive approach to regenerative medicine by delivering precise and targeted shockwaves through a focused applicator, it can concentrate energy on specific areas for highly effective treatment.

Softwave also simultaneously utilizes unfocused shockwaves to ensure a broader coverage of the affected area, maximizing the therapeutic benefits.

Other shockwave devices introduce micro-trauma to induce cell healing, but Softwave Tissue Regenerative Technology does not. Instead, it directly delivers healing energy into your tissue to activate stem cells that trigger self-repairing.

Softwave Tissue Regenerative Technology uses a special process called electrohydraulic shock wave generation. It works in three parts:

- First, an electrode is placed in a water-filled reflector at a specific point.
- Then, a burst of high voltage is sent to the tips of the electrode, just like a bolt of lightning. This creates a quick electric spark between them. This spark turns the water into vapor, releasing a round shock wave as it escapes.
- This shock wave comes in two parts: first, a gentle wave spreads out like ripples on a pond, and then a focused wave goes to a specific point. This results in the treatment having a conical area of effect where the applicator is applied.
- When Softwave touches your cells, they wake up something called mechanoreceptors. They make the cells do crucial things, like releasing special molecules that help you heal and grow.

Instead of causing harm, Softwave tricks your body into thinking it has been injured. Here's how it works:

- The waves cause the walls of cells in a specific area to become more like doors, allowing proteins to pass through.
- These proteins, known as exosomes, act like messengers and mimic cellular injury.
- This tricks your body into starting a biological cascade, like a chain reaction of healing. It includes generating stem cell attractants, which allow stem cells to direct the repair of the treated area.

## What are the recommended instructions for post-treatment care following Softwave treatment sessions?

The Softwave Tissue Regenerative Technology stimulates an inflammatory response, the body's natural healing process. Therefore, it is crucial to refrain from using anti-inflammatory medications (such as aspirin, Advil, Motrin,

Aleve, and Naprosyn) and apply ice after the Softwave treatment. If you experience pain, it should subside within 24 hours. You may use over-the-counter non-anti-inflammatory pain medications (such as Tylenol) if necessary, provided you have no known issues with this medication. In addition, you should decrease activity for 48 hours following the treatment.

Staying hydrated is critical to promote healing after your treatments. Please read the information on the Centers for Disease Control and Prevention to learn more about proper hydration:

[https://www.cdc.gov/healthyweight/healthy\\_eating/water-and-healthier-drinks.html](https://www.cdc.gov/healthyweight/healthy_eating/water-and-healthier-drinks.html)

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## Medical Conditions Disclosure:

I have informed my therapist(s) of any conditions that may limit my ability to undergo an evaluation or treatment in the perineal/pelvic region, including the

delivery of ultrasonic healing waves to the lower pelvic area, vagina, and/or rectum. With this understanding,

We want you to be informed of all aspects of this treatment. By signing the consent section on our New Client Intake Form, you acknowledge that you understand and accept the risks and benefits of shockwave therapy and consent to have this therapy administered.

## OPEN COMMUNICATION for Issues and Concerns

While Softwave therapy is a revolutionary, cutting-edge technology that has shown significant benefits for many patients, it is not a one-size-fits-all solution. Some individuals may experience varying degrees of improvement, while others may not respond as expected.

In the medical field and therapy world, it's essential to understand that **no treatment or therapy can come with a guaranteed outcome for every individual.** Each person's body responds differently, and various factors can influence the effectiveness of a treatment, including the nature and severity of the condition being treated, overall health, and individual response to therapy.

It's important to note that our therapists are highly trained and dedicated to providing the best possible care. We strive to offer treatments that are backed by research and have proven efficacy. However, **we cannot guarantee specific results or outcomes.**

Please monitor your voicemail and texts to ensure that, in a rare case, there might be a change to your appointment.

We encourage **OPEN COMMUNICATION** and collaboration throughout your treatment journey. If you have any concerns or questions about your treatment plan or the expected outcomes of Softwave therapy, please **contact the Owner, Kun-Yen Kuo. You will receive a phone call within 24 hours** to discuss your concerns. Your comfort, understanding, and satisfaction are our top priorities, and we are here to support you every step of the way.

