The Use of Bioelectric Stimulation for Erectile Dysfunction

Client Treatment Consent and Release

Subject's Name: _____

Disclosure Statement

Your healthcare provider is an investigator of this research protocol, and as an investigator, is interested in both your clinical welfare, as well as the conduct of this study. Before entering this study, or at any time during the study, you may ask for a second opinion about your care from another doctor who is unaffiliated with this study. You are not under any obligation to participate in any research offered by your health care provider, and refusal to participate will not influence your care in any way.

Purpose of this Study

This study is designed as a post market evaluation to investigate the safety and effectiveness of using bioelectric stimulation to increase the levels of healing proteins to improve blood circulation, heal muscle, improve nerve connections if possible and reduce inflammation all with the intent to relieve some or all of the symptoms erectile dysfunction (ED).

Note - The current FDA 510K market clearance for the stimulator to be used in this study is only for improving blood circulation and muscle atrophy recovery and improvement of muscle motion at this time. All of these cleared indications of use are believed to have a potential tie to erectile dysfunction symptoms relief. This study purpose is to evaluate more closely and carefully that direct connection.

Procedures

By participating in this study and signing this consent and release form, you will be asked to undergo the following procedures:

1. Answer questionnaires related to your ED as well as your ability to carry out various activities relate to sexual health.

2. Be present for an initial and post treatment examinations.

3. Be present for the 4 weeks of bioelectric stimulation-treatment 2X a week for 30 to 45 minute each.

4. Treatment sessions are 30 to 45 minutes in duration and must be completed at least twice per week. If more than one treatment week is missed due to absence, you will be excused from the treatment study.

5. Undergo a blood draw both before and at the end of this study to measure the serum levels of the proteins of interest (such as klotho) and correlate with improvement in organ function and overall sexual health.

Participation and Withdrawal

If you decide to participate, you are free to withdraw consent and discontinue participation at any time without prejudice to your future care this clinic. You have the right to to refuse to answer any question that you prefer not to answer on the questionnaires. Any questions you have in regards to the procedure can be answered by contacting cs@lionhearthealthstim.com

No Financial Compensation But Discounted Fees

There will there not be any compensation for participating in this study. By participating in the study you will receive 40% discounted fees on all stimulation and clinic services and related products.

Potential Risks, Discomfort, and Benefits

I acknowledge that bioelectric stimulation treatments and related biologics procedures, if any, have been used successfully with minimal if any discomfort or side effects reported in over 1,000 patients when used for a variety of indications. There are no specific guaranties that can or have been made concerning the outcome related to both safety and efficacy. I understand clearly and fully that the stimulation device being used in these procedures only has FDA 510K market clearance for these indications of use: 1. Improving blood circulation. 2. Mild pain relief including inflammation related pain. 3. Improving muscle motion and muscle atrophy recovery. I understand that some clients may experience more change and improvement than others. In virtually all cases, multiple treatments are required in order to realize a difference.

Release of Liability:

I understand and agree to fully and undeniably assume the risks and hazards as described above which may occur in connection with the treatment involved in this study including, but not limited to: lack of any measurable benefit-unsatisfactory results, pain, discomfort, redness, blistering, scarring, infection, and change in skin pigmentation, muscle damage, and increased hair growth. I understand that even though precautions may be taken in my treatment, not all risks can be known in advance. I further understand that the above may not improve my condition being treated. I also understand that the response to treatment varies on an individual basis, and that beneficial results are not guaranteed. I have fully disclosed on my client intake form any medications, previous complications, or current conditions that may affect my treatment. I understand and agree that any legal action of any kind related to any treatment I receive will be limited to binding arbitration using a single arbitrator agreed to by both parties. I also understand that the company, its employees, its advisors, board directors, suppliers and clinical collaborators in no way make any claim(s) that the device or methods have been proven safe or efficacious for the purposes of treating my

condition. Improving blood circulation, relieving pain and improving muscle motion may possibly help with my condition but may not. Therefore, in consideration for any treatment received, I agree to unconditionally defend, hold harmless and release from any and all liability the company and the individual that provided my treatment, the insured, and any additional insureds, as well as any officers, directors, or employees of the above companies for any condition or result, known or unknown, that may arise as a consequence of any treatment that I receive.

Photographs and Data Use Release:

In consideration for treatment received, I hereby grant permission to the individual or company that provided my treatment to use any photographic treatment or other records for the purposes of clinical and statistical studies, advertising, publication, or promotion without any additional compensation to me.

_____ Date:

Signature of Research Participant

_____

Printed Name

_____Date: _____

Principal Investigator