

# INFORMED CONSENT

with providing the service Planar Shockwave Therapy for the treatment of

**Erectile dysfunction caused by restricted blood flow into the cavernous bodies of the penis**

**Induratio penis plastica, otherwise known as Peyronie's disease**

Client:

Name and Surname: .....

Date of birth: .....

## DEFINITION OF THE PROBLEM:

### Erectile dysfunction

Physiologically, penis has rich vascular blood supply. Smaller vessels supply the cavernous bodies during sexual stimulation, which contain most of the blood in the penis during erection. Restricted blood flow into the cavernous bodies leads to erectile dysfunction, i.e. inability to have sexual intercourse (inability to insert penis into vagina), the cavernous bodies are not supplied with oxygen, fibrosis of the cavernous bodies (pathological rebuilding of the elastic tissues), psychological issues connected to the inability to have sexual intercourse and disruption of relationships. Restricted blood flow into the penis can be a symptom of a different problem, e.g. high blood pressure, high levels of cholesterol, sclerosed veins or diabetes. The treatment plan for these problems is treatment with planar shockwave therapy.

### Peyronie's disease

The essence of this disease is the process of scarring and fibrosis affecting the axillary bodies of the penis, originating from the tunica albuginea (sheath enveloping the axillary tissue of the penis). It causes the formation of fibrotic scar tissue, the so-called solid plaques, which cause pain, curvature and deformity of the penis, usually during an erection. Therefore it is an abnormal activation of the wound healing process with the formation of a solid scar. It is considered, that one of the most likely causes, but not the only one, may be recurrent microtraumas during sexual intercourse at the microvascular level. Probably a hereditary predisposition also plays a role.

## SPECIFICATION OF THE METHOD:

Planar shockwave is a physical therapy functioning on the principle of the electromagnetic induction. All the energy emerging from the machine is accumulating in the acoustic lens, during the application the energy permeates deep into the tissue of the penis. Single-pulse waves with high frequency, small width of pulse and short start-up time are emitted through a special elliptical applicator and are focused onto an area with a diameter of a few millimeters. This secures application on a narrowly defined area even in the deepest tissues of the penis

## PURPOSE AND GOAL OF THE TREATMENT:

The treatment with shockwaves therapy is non-invasive, during which the tissue structure is naturally recovered and regenerated. The shockwaves directly affect the blood vessels with restricted function and cause them to "open", therefore it treats the whole illness, and does not just eliminate the symptoms.

### Erectile dysfunction

The purpose of the treatment is to completely erase the problem or significantly lower the amount of medication needed to support erection.

### Peyronie's disease

The purpose of the treatment is reducing the pain, discomfort and other symptoms negatively affecting the patient's sexual and everyday life.

## EFFECTIVITY OF THE TREATMENT:

Effectivity is individual. First improvement can be expected after 3 weeks of rest after the first treatment cycle.

### Erectile dysfunction

Application of the shockwave affects the vascular cause of erectile dysfunction. If another cause is present it's important to talk to your doctor (urologist, sexologist, andrologist) about further treatment.

### Peyronieho Choroba

Treatment is effective in relieving pain (in studies, 53% of men reported complete resolution of pain, 30% reported reduced pain, 9% reported the same condition and only 6% of men reported mild deterioration). The effectiveness of the change in the curvature itself is individual.

## DESCRIPTION OF THE TREATMENT CYCLE:

### Erectile dysfunction

Before the start of the treatment client is required to obtain a recommendation letter from their doctor. Once the client's doctor agrees, client undergoes therapy twice a week for three weeks. If client is not capable of coming in twice a week it is important to keep the applications no longer than one week apart. The reason is to keep the tissue active. This cycle is followed by a 3 week pause, which is the phase of capillary vessel growth. After this time, the entire cycle can be repeated again if necessary. Another cycle would be ideal to undergo after 12 months at the earliest.

### Peyronieho choroba

Before the start of the treatment client is required to obtain a recommendation letter from their doctor. Once the client's doctor agrees, client undergoes therapy once a week for at least 6 therapies. This cycle is followed by a 3 week pause, which is the phase of capillary vessel growth. After this time, the entire cycle can be repeated again if necessary. Another cycle would be ideal to undergo after 12 months at the earliest.

## DESCRIPTION OF THE THERAPY:

Client showers at home before each therapy. The application is not painful, though it may cause a light erection. The length of one application is approx. 15 min.

### **Erectile dysfunction**

At each visit, both cavernous bodies are homogeneously affected at each side, as well as the body tissues at the base of the penis from the side and from below. During one visit 1500 pulses are applied.

### **Peyronie's disease**

The individual pulses are applied especially into the fibrous scar and to the axillary bodies. During one visit, approx. 1500 pulses are applied.

## EXPECTED CONSEQUENCES AND CONSEQUENCES OF THE APPLICATION

Unlike conventional erectile dysfunction treatment, the use of shock waves does not require any other drugs (sedatives, anesthetics, etc.). In addition, shockwave therapy does not cause any unwanted effects or systematic burden on other organs and healthy tissues. Very rarely, mild swelling, redness or hematomas (i.e. "bruises") may occur. These reactions are associated with increased blood flow to the skin of the penis and usually resolve within 1-3 days after the procedure. Treatment is not suitable for acute oncological diseases.

## POSSIBLE RISKS

Before the start of the treatment client is **required to obtain doctor's recommendation for the treatment**. With the recommendation doctor confirms, that client is suffering from erectile dysfunction due to a vascular cause, and that client does not currently suffer from any oncology and sexually transmitted diseases.

## ALTERNATIVE TREATMENT

It is important to differentiate between the treatment of the problem's symptoms and treatment of its cause. Due to a sufficient number of non-invasive solutions, the number of patients requiring surgical treatment is decreasing.

1. Pharmacological treatment: treatment of the symptom, not the cause. Pill is being aided during recommended period of time before sexual intercourse and the length of the effectivity is depending on each pill individually. Sexual stimulation is always needed for realization of sexual intercourse. Here is some medication treating erectile dysfunction: Viagra, Cialis, Levitra, Spedra. (in both ED and PD)
2. Injective treatment: the treatment is about auto-application of the vasoactive substance into one of the cavernous bodies of the penis. In 5-15 minutes the injection evokes erection without the need of sexual stimulation. The application requires a certain level of experience. The amount of the dosage and sensitivity of the patient can cause skin redness, sweating, hot flashes, general weakness, increased heart rate, lowered blood pressure or dizziness.

3. Vacuum pumps (erectile dysfunction): Method effective for every type of erectile dysfunction. It works on the principle of vacuum, which concentrates the blood into the cavernous bodies, which passively leads to erection. This method is not ideal for patients with coagulopathy, sickle cell anemia, and users of medication affecting the coagulation of blood.
4. Surgical treatment: According to the type of dysfunction there are different surgical solutions. In case of a vascular problem surgeon increases the restriction of the vascular drainage system. If the problem is caused by insufficient blood supply of the cavernous bodies, for example after pelvic injury, the patient may undergo anastomosis (connection of blood vessels), which leads to increased blood flow and therefore increases the vascular resistance.

**CLIENT'S LIMITATIONS CAUSED BY THE APPLICATION:**

Planar shockwave therapy does not affect the client's daily life, work life or health condition. Client arrives for the appointment and immediately after the application is capable to continue in his usual daily activities.

**INFORMATION ON THE TREATMENT REGIMEN AND OTHER IMPORTANT MEASURES:**

The therapy demands to follow the treatment cycle mentioned above. Other than this there are no specific precautions to follow. There is no need to avoid physical exertion or sexual activity.

**I declare that I am not aware of any:**

- currently occurring oncology disorder.
- currently occurring sexually transmitted (infectious) disease.

**I declare that I have been informed about my right to ask questions and freely make a decision about agreeing or disagreeing with the suggested treatment or procedure.**

**I declare that I understand the given information, I do not have any more questions and hereby give you freely my informed consent with services stated above.**

**Date:** .....

**Signature of the client** .....

**Signature of the informing therapist:** .....