Dear Patient,

Thank you very much for your interest in Extracorporeal Pulse Activation Technology (EPAT®) for the treatment of _________________.

The procedure consists of applying a unique and proprietary set of acoustic pressure (sound) waves that are generated outside the human body to the treatment area via the device applicator. On behalf of the knowledge and experience gathered to date, these acoustic pressure waves do not cause any clinically relevant side effects.

Our patient information sheet is intended to inform you of any/all possible risks associated with the EPAT® treatment and the benefits of this new non-invasive procedure.

Introduction:

High-intensity acoustic pressure waves, often called shock waves (ESWT or ESWL), have been used in medicine for more than twenty years. This procedure is considered the “Gold Standard” in urology for the fragmentation of kidney stones.

This non-invasive treatment method, which has proved its efficacy for many years and in millions of cases, utilizes focused acoustic pressure waves (shock waves) to disintegrate kidney and other urologic stones without invasive surgery.

During the last few years, acoustic pressure waves (EPAT®) have been used in areas of orthopedics, traumatology, rheumatology, pain management, and rehabilitation with great success.

In your specific case, this unique set of acoustic pressure waves (EPAT®) will be applied to the target region identified by your doctor.

Our Objectives – Your Benefits:

The innovative, non-invasive treatment is intended to treat root cause of your injury using a proprietary set of unique acoustic pressure waves to achieve the best possible clinical outcome and therapeutic effects of treating _________________________ and surrounding connective tissue.

In your case, the EPAT® treatment will stimulate a cellular expression and improve blood and lymph circulation and thus accelerate the healing response and tissue regeneration. Moreover, faster blood and lymph circulation may also stimulate collagen production and fibrotic tissue breakdown in the treatment regions. As a result, we expect to see improvements in both pain reduction and functionality.

Possible Risks of EPAT® Treatment:

The non-invasive Extracorporeal Pulse Activation Treatment (EPAT®) has virtually no risks or side effects. In some cases, patients may experience some minor discomfort during and immediately following the procedure. Side effects from EPAT may include minor skin bruising, reddening, and swelling around the treated area.
Preparation:

Your treatment provider will ensure that you are positioned for treatment in such a way that the applicator can be coupled to the target region. Ultrasound gel will be applied before the applicator is positioned on your skin surface.

The number of pulses to be applied depends on your specific diagnosis. The energy can be gradually increased based on your specific sensitivity levels. The treatment provider will then "scan" the treatment region with the applicator.

Procedure:

EPAT® treatment will be performed on _______________________. Ultrasound gel will be used to ensure perfect coupling of the applicator to your skin.

Each treatment session will take approximately 5-10 minutes. One treatment per week for a total of 3-5 treatment sessions will take place over a 2-4 week period. During this time, it is necessary to discontinue use of any/all NSAIDS and drink plenty of water before and after the treatment.

Your doctor will document the diagnosis, number of treatments, applicator selection, energy and frequency settings, number of pulses administered, pain scale, and range of motion, if/when applicable.

After the treatment-period there will be two follow-up visits required. You will be asked about your personal experience and your overall impression of your EPAT treatment which your doctor will document.

Contraindications:

The safety and effectiveness of the EPAT procedure has not been determined on people with the following health conditions. Your doctor will provide you with information about how these and other conditions might affect the decision to perform EPAT procedures.

- Serious cardiovascular disorders
- Implanted cardiac pacemakers that are not approved for pressure wave treatment
- Malignancies
- Pregnancy, breast-feeding
- Phlebitis or deep venous thrombosis in leg

Thank you very much for your interest and cooperation.

Physician Name: __________________________________________

Practice Name: __________________________________________

Date: __________________________________________