

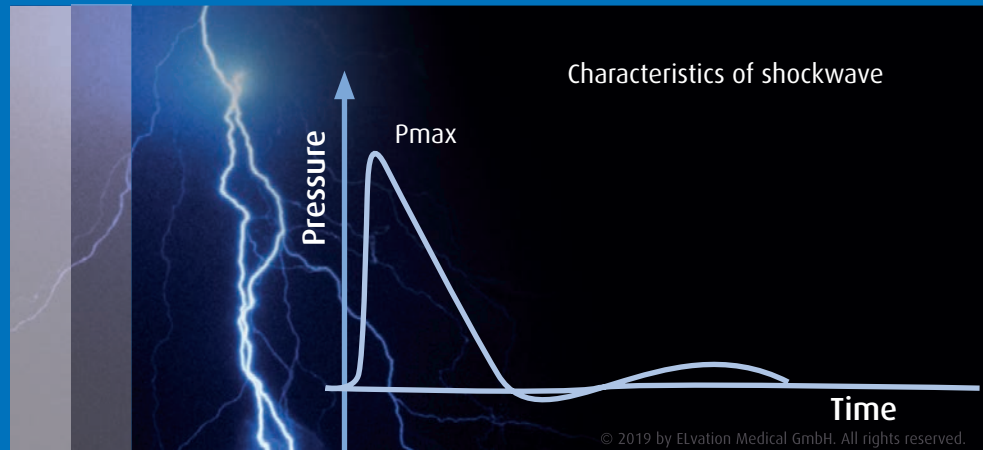
PiezoWave² ESWT/UROLOGY

Using PIEZO shockwaves to treat the urogenital tract



Physical principles of acoustic shockwaves

Shockwaves consist of strong, expansive, acoustic pulses which have an extremely short rise time of just a few nanoseconds. This is followed within just a few microseconds by a brief period of negative pressure and a subsequent gradual reversion to normal pressure.

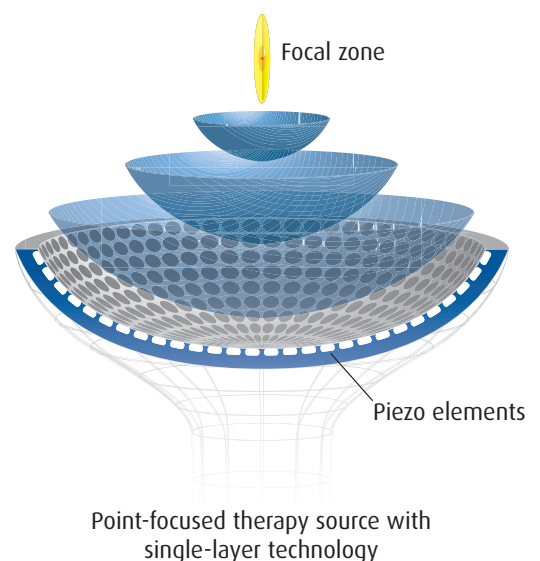
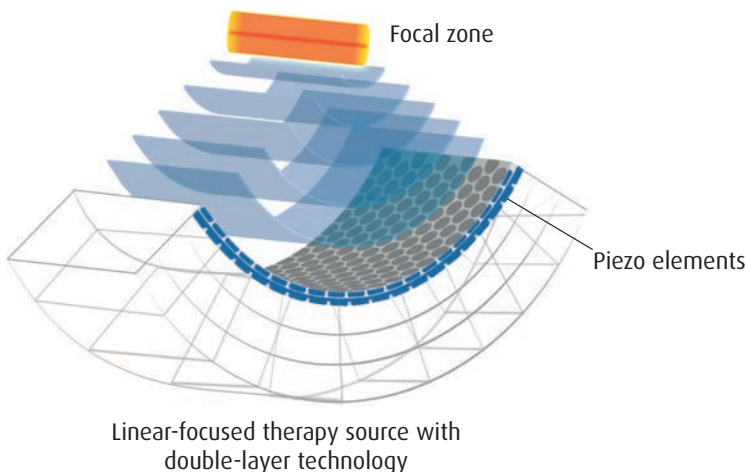


Efficacy of focused ESWT

Extracorporeal shockwaves are mechanical stressors which are able to induce biochemical changes in living tissue. This process is known as mechanotransduction.

Scientifically described mechanisms of action:

- Induces neovascularization
- Promotes local circulation and suppresses proinflammatory processes
- Induces secretion of growth factors such as TGF- β 1, VEGF
- Stimulates mesenchymal stem cell migration
- Antibacterial effect
- Stimulates fibroblast proliferation



The piezoelectric principle / superior and focused

A high-voltage pulse is used to excite piezo ceramic elements arranged on a concave surface, causing them to briefly and simultaneously expand by a few micrometers to create a pressure pulse. The piezo elements are precisely aligned with the therapy focus. Precise focusing results in a steepening, with the shockwave forming at the focus of treatment. This makes the piezo shockwave the only shockwave method to use “direct focusing”. This technology accounts for the precise, well-defined focal zone. Applications are quiet and virtually painless and the intensity of the energy levels can be freely adjusted. Piezo shockwave technology is known for its exceptional durability.

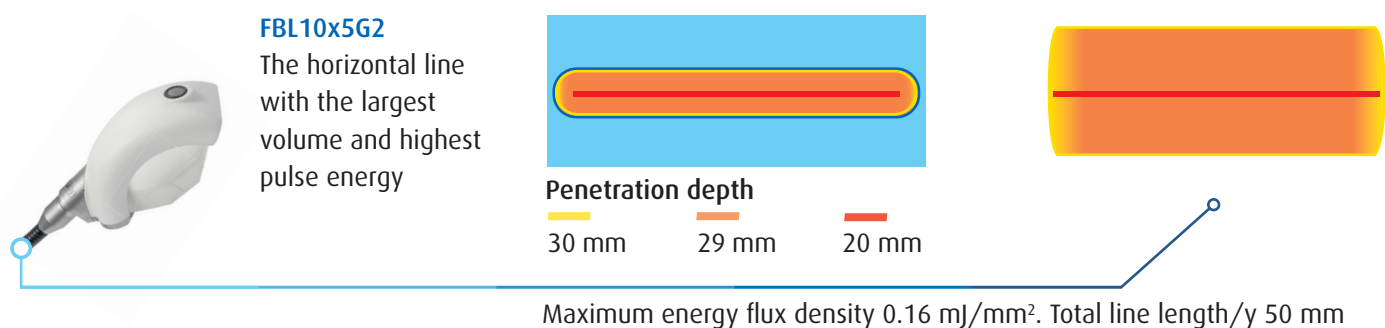
The right therapy source for every requirement

As the number of indications for shockwave therapy have increased, the demands on the focal zones of shockwaves in terms of their penetration depth, strength, shape and volume have also substantially increased. ELvation Medical and Richard Wolf set themselves the task of developing the right therapy source and focal zone for many different indications to ensure that the right therapy source would be available to deliver promising, optimally adapted treatment.

Linear therapy focus

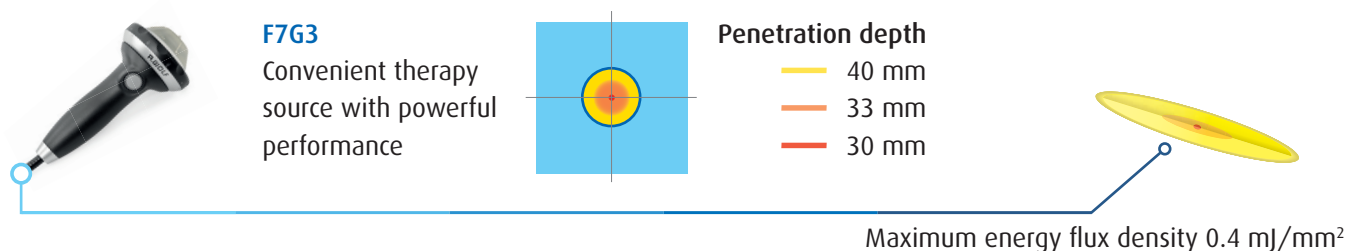
Unparalleled for the treatment of erectile dysfunction (ED)

Richard Wolf and ELvation developed a linear-focused shockwave, an innovative approach that was the first of its kind worldwide. The aim was to make the application of focused shockwaves faster, more uniform and more effective.



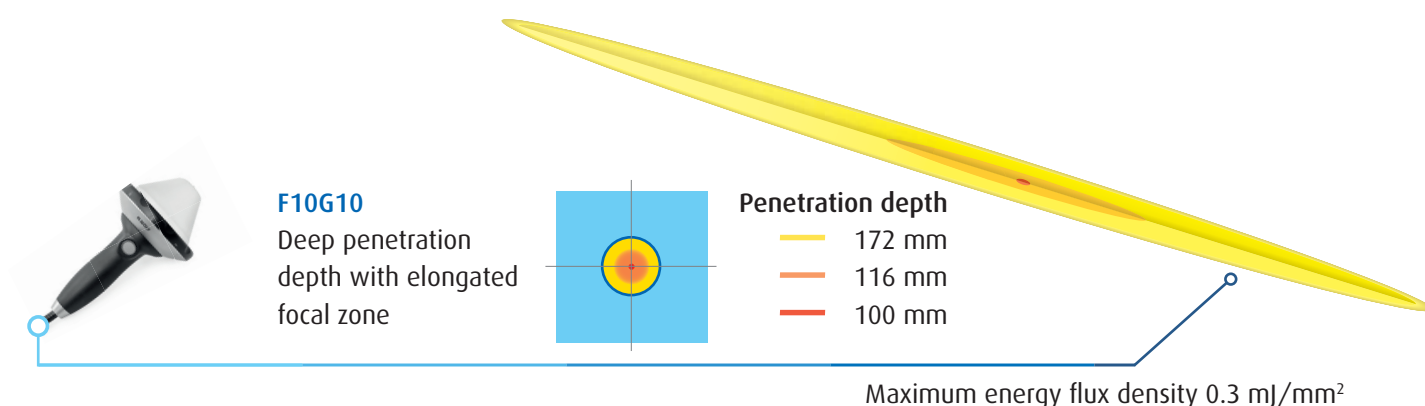
Convenient and powerful to treat induratio penis plastica (IPP)

The F7G3 therapy source is a small convenient therapy source. Its powerful performance makes it ideal to treat IPP.



Elongated focal zone to treat chronic pelvic pain syndrome (CPPS)

The F10G10 therapy source creates an elongated focal zone which is especially suited to treat the anatomy of the pelvic floor. The maximum penetration depth of the focal center is 100 mm. This is particularly useful when treating sites at different depths – it is not necessary to change the gel pad.



Linear Shockwave Tissue Coverage (LSTC-ED)

A unique therapy concept to treat ED

Based on sufficient evidence, the EAU Guidelines now consider low-energy focused shockwave therapy to be a first-line therapy. The application of point-focused shockwaves (Fig. 1) to treat vascular erectile dysfunction (ED) has already been achieving good results for some time.

The continued development of the piezo shockwave technology together with a therapy source with an extended, linear-focused therapeutic focus has led to a further important breakthrough. The combination of these two with the new optimized LSTC-ED therapy concept has led to a significant improvement in the application technique and the treatment results.

The convenient piezo therapy source creates a linear-focused shockwave, which can be used to treat the entire length of the corpora cavernosa quickly and comprehensively (Figs. 2/3). At the start of treatment, the therapy source is placed at right angles to the corpora cavernosa and moved along the length of the penis (the corpora cavernosa) and across the perineum (the crura penis) (Fig. 4).

This ensures a maximum uniform application of energy, making it possible, for example, to apply 5000 pulses within a treatment time of just 15 minutes. The penetration depth is 10-15 mm. Treatment is largely painless and should be carried out 1-2 times per week for a total of 4-6 treatment sessions.

© 2019 by Elvation Medical GmbH.
All rights reserved.

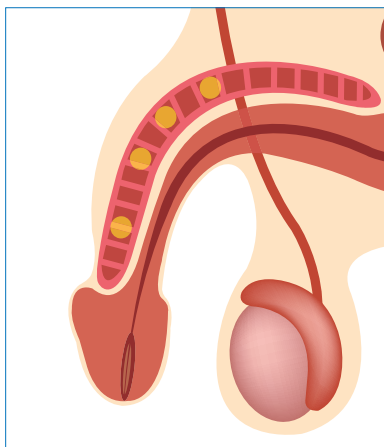


Fig. 1: Primary focused or defocused treatment

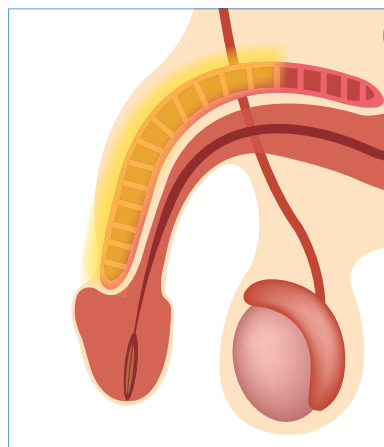


Fig. 2: Linear-focused shockwave therapy using the LSTC-ED technique along the corpora cavernosa

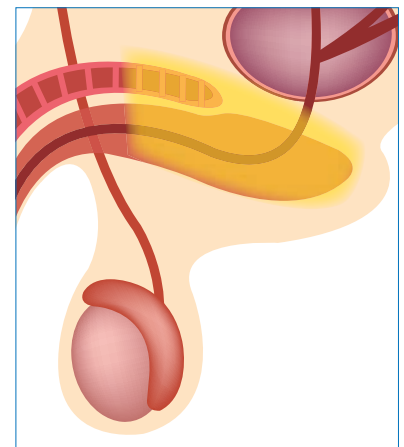


Fig. 3: Linear-focused shockwave therapy using the LSTC-ED technique along the crura penis

Effective, comprehensive and quick

Unique uniform treatment of target tissue with the PiezoWave2 and the FBL10x5G2 therapy source.

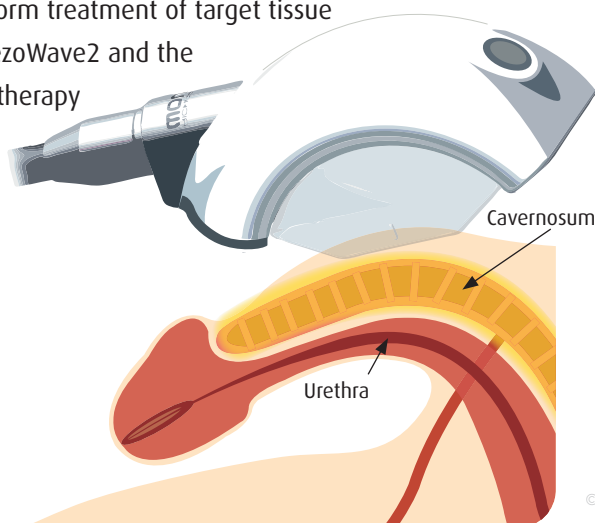
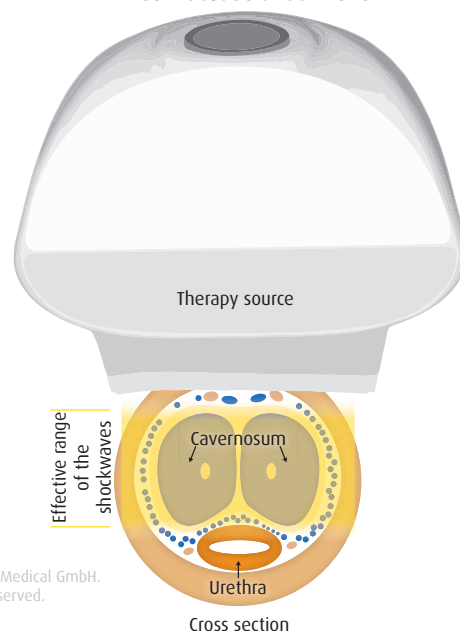


Fig. 4: Applying a linear-focused shockwave



© 2019 by Elvation Medical GmbH. All rights reserved.

Treatment using the LSTC-ED technique and the PiezoWave²

We have taken all possible care with regard to the research and the clinical approval of this procedure. Reliable evidence and studies are important for us. A prospective, multicenter placebo-controlled study (*) with 75 patients showed a significant improvement in IIEF-5 scores, with

successful outcomes reported for 81% of patients after one month. Improved functionality was also verified at 6 months after treatment, confirming the long-term effect of treatment with the LSTC-ED technique.

LSTC-ED algorithm

Based on the experience of Motil et al. with the LSTC-ED technique, we can recommend the best possible protocol for working with the PiezoWave2 using the LSTC-ED technique. Uniquely, the experience obtained with this technique have been mapped as an algorithm, which is exclusively available to us.

This algorithm** makes it possible for the first time to adapt the settings and number of applied pulses to the individual patient.

*(The results of the algorithm are based only on empirical data and their applicability must be verified by the medical user.)

The LSTC-ED algorithm, tailored treatment of ED using the LSTC-ED technique, suggested number of shocks.

This algorithm is the first of its kind and suggests the optimal number of shocks (and thus the energy dose) to be applied to cavernosal tissue during a single session for vasculogenic erectile dysfunction using low-intensity focused shock waves.

The algorithm was created under the aegis of Dr. Igor Motil based on his own experience and his studies of this type of treatment. The aim was to improve treatment outcomes by tailoring the treatment to each individual patient. The algorithm takes major factors that can influence treatment results into account, such as the patient's initial IIEF-5 score and comorbidities. However, it should be emphasized that medical science is still evolving and Dr. Motil reserves the right to make changes in the future.

This LSTC-ED algorithm is only suitable for use with Richard Wolf Elvation PiezoWave2 shockwave systems in conjunction with the linear therapy source FBL10x5G2. We do not recommend using this algorithm with other devices which have very different shockwave shapes, shockwave locations, and applied energy.

Suggested treatment protocol:

Intensity: 25
Frequency: 6-8 Hz
Total number of sessions: 4 to 6 over a period of 14 to 30 days
Interval between sessions: weekly or on an interval of at least 3 days.

Form fields:

- IIEF-5 score: (0-4)
- ED duration: (1-12)
- Hypertension: (0-1)
- Diabetes: (0-1)
- CHD: (0-1)
- Smoker: (0-1)
- BMI over 25: (0-1)

Submit

For further information see
www.ed-stosswelle.de,
www.ed-shockwave.com
www.ondedurto-de.it.

* Motil, I., Kubis, I., Sramkova, T.: Treatment of Vasculogenic Erectile Dysfunction with Piezowave² Device. Application of Low Intensity Shockwaves Using Novel Linear Shockwave Tissue Coverage (LSTC-ED®) Technique. A Prospective, Multicenter, placebo-controlled Study. Advances in Sexual Medicine, 2016, 6, 15-18.

The piezo shockwave - Strong performance to treat induratio penis plastica (IPP)

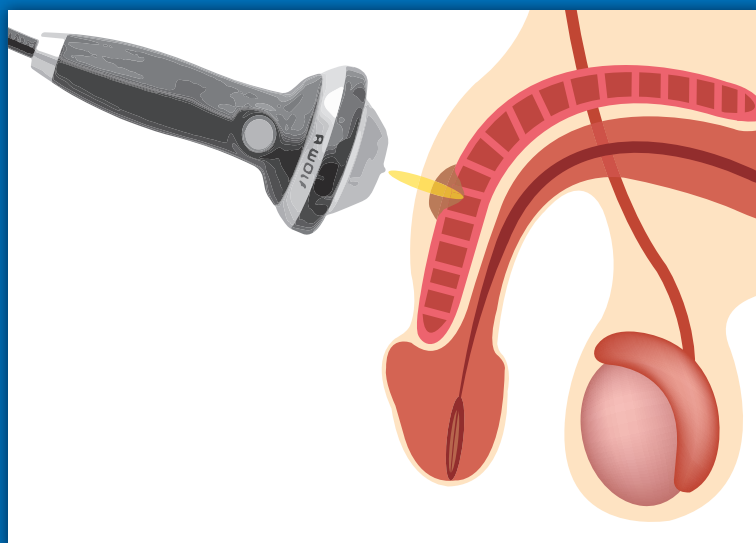
Induratio penis plastica (Peyronie's disease) is an acquired, usually chronic disease characterized by excessive fibrosis of the tunica albuginea of the corpora cavernosa. The disease occurs in two phases and leads to more or less pronounced penile deformation. The prevalence of IPP increases with increasing age. The precise cause of the disease is still unclear, although a genetic component appears to play a role.

Previously existing treatment modalities were not very effective and/or were associated with numerous side-effects.

The introduction of shockwave therapy (ESWT) into the field of urology led to the development of treatment modalities which have now been incorporated in new and promising therapeutic concepts, including the treatment of IPP.

According to initial studies, a significant decrease in pain can be achieved after just a few treatment sessions of ESWT. Treatment can also prevent disease progression. According to the experience reported by users, treatment can lead to straightening of the curvature by a few degrees.

Calcifications are often found in the plaques formed in the tunica albuginea and can be treated directly using ESWT. Treatment is based on the patient's feedback and reported level of pain, and takes 6-7 minutes, during which 3000 pulses are applied. Treatment can be carried out 1-2x/week and should consist of 6-8 sessions in total. A penetration depth of 5-10 mm is usually sufficient. The convenient and compact F7G3 therapy source is particularly suited to treat IPP. Its powerful therapy focus is useful to precisely treat calcifications in the fibrous plaques.



Point-focused treatment
of calcified plaques

Fig. 5

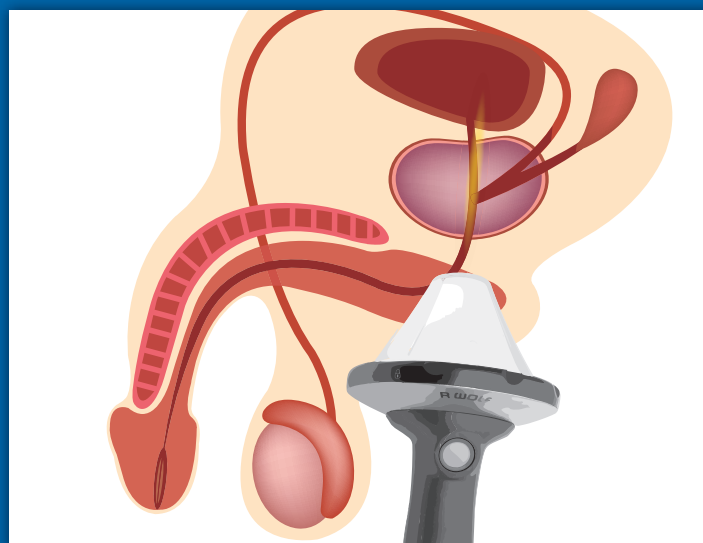
Elongated focal zone to treat chronic pelvic pain syndrome (CPPS)

Chronic pelvic pain syndrome (CPPS) is a multifactorial disorder with a largely unknown etiology. The different forms of presentation are categorized in accordance with the new NIH (National Institutes of Health) classification into: acute bacterial prostatitis, chronic bacterial prostatitis, inflammatory and non-inflammatory chronic pelvic pain syndrome, and asymptomatic prostatitis. Around 90 percent of patients suffer from chronic (nonbacterial) prostatitis/chronic pelvic pain syndrome.

Previously existing treatment approaches were often insufficient to help patients with chronic nonbacterial prostatitis. As the symptoms are not caused by bacteria, drug therapies are usually ineffective. Increased pelvic floor muscle tone is now being discussed as an additional factor which may be a causative factor for the pain.

Recent therapeutic approaches based on ESWT have shown promising results. ELvation Medical and Richard Wolf have developed a special therapy source to treat the pelvic floor, which takes the particular anatomy of the pelvic floor into account. The F10G10 therapy source generates an elongated focal zone and its focal center has a maximum penetration depth of 100 mm. The assumed 5 MPa therapeutic impact zone is elongated, with a penetration depth at the distal focus of up to 172 mm. According to the experience reported by users, a penetration depth of 40-60 mm is sufficient. However, the elongated focus makes it possible to cover the entire prostate together with the surrounding tissue. Trigger points in the muscles of the pelvic floor occur at varying depths of between 30-100 mm and can also be easily reached by the therapy focus. In addition, the surface area of the gel pads placed on the skin is relatively small, which is an advantage in perineal applications where space is limited.

Treatment is based on the patient's feedback and reported level of pain, and takes 6-7 minutes, during which 3000 pulses are applied. Treatment can be carried out 1-2x/week and should consist of a total of 6-8 sessions.



Elongated focal zone to
treat chronic nonbacterial
prostatitis

Fig. 6

**All information in this brochure related to settings, application sites, duration of applications, and general use of the technology is based on clinical experience and is given for training purposes. However, the applicability of these data must be verified by the medical end-users who have been trained to use shockwave systems. This brochure cannot replace the currently valid statements provided in the guidelines of DIGEST, ISMST and the user manuals of the respective shockwave systems.

Contraindications for ESWT

In principle, there are few contraindications for ESWT. The user manuals of ESWT systems contain the most recent information on contraindications. Some of the contraindications listed in the user manuals of therapy sources by Richard Wolf include:

- After radical prostatectomy
- Active tumor disease (especially in the area of the prostate and pelvis)
- Penis prostheses
- Coagulation disorders (a prior check of the coagulation status may be necessary)
- Hypogonadism
- Taking blood-thinning medication
- etc.

Reference note

Sramkova T, Motil I, Jarkovsky J, Sramkova, K: Erectile Dysfunction Treatment Using Focused Linear Low-Intensity Extracorporeal Shockwaves: Single-Blind, Sham-Controlled, Randomized Clinical Trial. Urologia Internationalis 2019 December. DOI: 10.1159/000504788.

Motil, I, Kubis, I, Sramkova, T: Treatment of Vasculogenic Erectile Dysfunction with Piezowave2 Device. Application of Low Intensity Shockwaves Using Novel Linear Shockwave Tissue Coverage (LSTC-ED®) Technique. A Prospective, Multicenter, placebo-controlled Study. Advances in Sexual Medicine, 2016, 6, 15-18.

Zimmermann R, Hölzl L: Extrakorporale Stoßwellentherapie - Behandlungsoption bei CPPS. Eine neue Behandlungsoption des Chronischen Beckenschmerzsyndroms scheint hohe Wirksamkeit bei geringen Nebenwirkungen zu zeigen.

Jordan R, Krieger MD, Paul J, Rizk MD et.al.: Shockwave Therapy in the Treatment of Peyronie's Disease. Sexual Medicine Reviews Volume 7, Issue 3, July 2019, 499-507.



ESWT/ESWL Team of



spirit of excellence

Distribution for Switzerland:



MTR - Health & Spa AG
Fällmisstrasse 64
CH-8832 Wilen b. Wollerau

+41 (0)44 787 70 80
info@mtr-ag.ch
www.mtr-ag.ch

