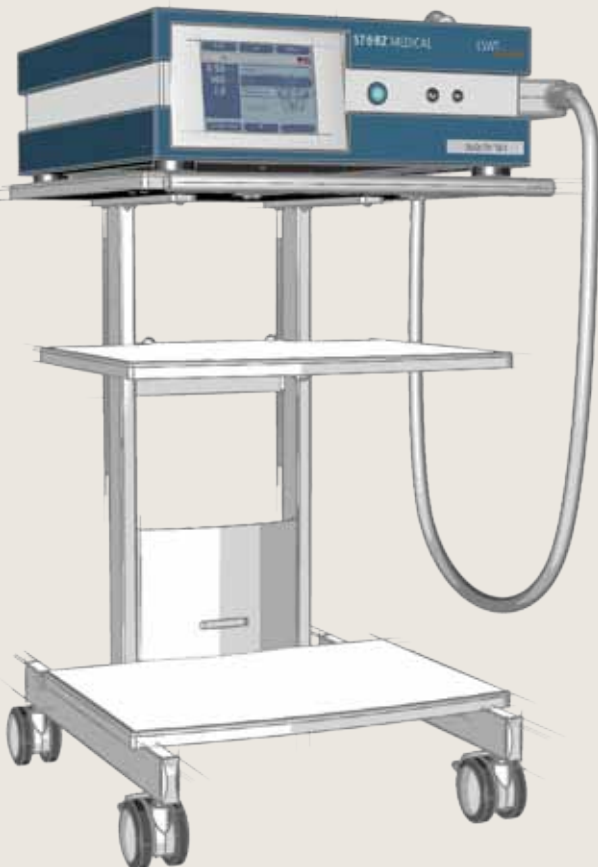


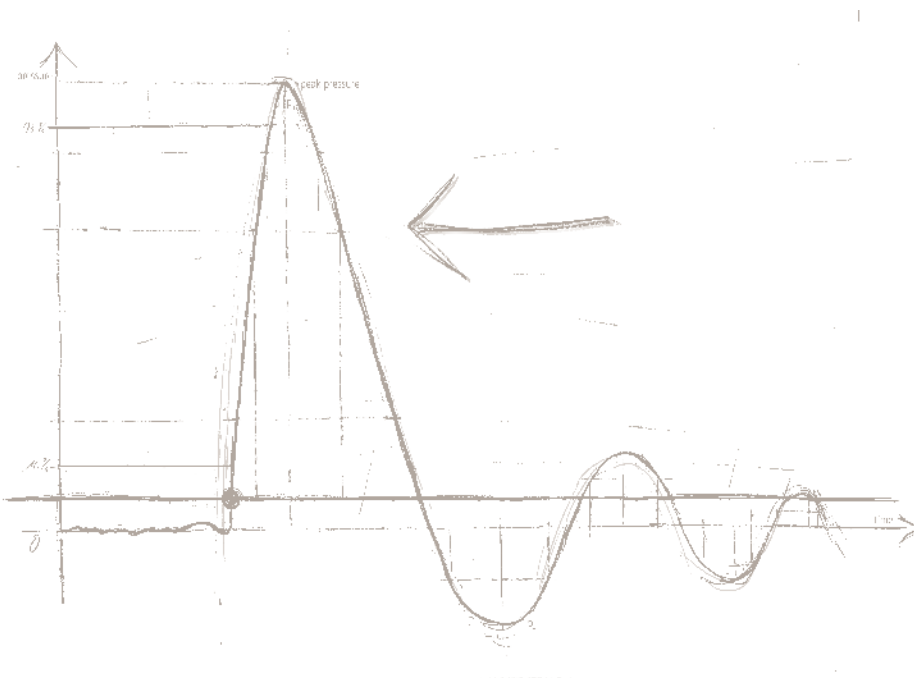
DUOLITH® SD1
The **FIRST** shock wave system
for urological pain therapy



Introduction to shock waves

Shock waves have led to revolutionary changes in urological stone therapy and have considerably expanded the therapy spectrum for orthopaedic indications like tendinopathies, pseudarthroses and more.

In contrast to shock waves with high energy, which are used for lithotripsy, shock waves with low energy have proven successful in stimulating nerve cells, metabolism and circulation, as well as providing lasting pain relief. Effective shock wave therapies have become established therapies in the treatment of different orthopaedic indications and in the area of angina pectoris in cardiology. Drawing on a vast base of expertise in the field of shock wave technology and therapy, STORZ MEDICAL - in cooperation with renowned medical institutions - has developed a shock wave therapy method for chronic pelvic pain (CPPS: Chronic Pelvic Pain Syndrome).



The mechanical effect of shock waves on the tissues stimulates the nervous system (memory effect of the central nervous system), distribution of the substance P and the release of nitrogen and other messenger molecules¹. Some of the effects include the activation of ion channels in cell membranes, an increase in metabolism and neoangiogenesis and the release of vascular endothelial growth factors that ultimately lead to pain reduction even for chronic pelvic pain.

¹ O. J. Wess, A neural model for chronic pain and pain relief by extracorporeal shock wave treatment, Urol Res, 36:327 – 334 (2008)

DUOLITH® SD1

for urological pain therapy

DUOLITH® SD1 is an effective and long-term treatment for Chronic Pelvic Pain Syndrome (CPPS) and Induratio Penis Plastica (IPP). Scientific studies have proven the effectiveness of focused shock waves on both indications.

Focused shock waves are used in the treatment of CPPS and IPP. The effectiveness of this modern shock wave equipment is determined by the individually selectable, dynamic and powerful energy range and the therapeutic depth of focus that can be chosen. Deep-lying areas can be treated easily, with the large focus zone making it easier to access these areas with a high degree of accuracy.

»T-Top« Version

- ▶ Patented STORZ MEDICAL cylindrical source
- ▶ Integrated trigger button on the handpiece
- ▶ LCD touch screen
- ▶ Easy to transport



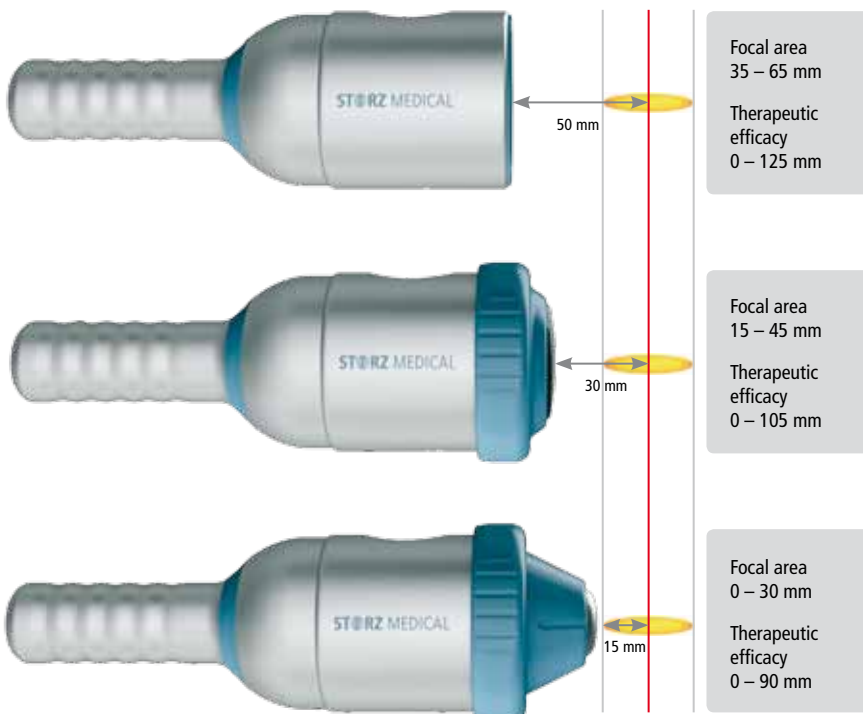
DUOLITH® SD1 CE 1275

Focused shock wave therapy

Focused shock wave therapy

- ▶ Dynamic energy range 0.01 – 0.55 mJ/mm² (max. 62 MPa)
- ▶ Selectable therapeutic penetration depth 0 – 65 mm
- ▶ High shock frequency 1 – 8 Hz
- ▶ Overall energy calculation

= outstanding STORZ MEDICAL cylindrical source



Use of stand-offs

The handpiece can be used with different penetration depths:

- ▶ without stand-off (CPPS)
- ▶ with stand-off I
- ▶ with stand-off II (IPP)

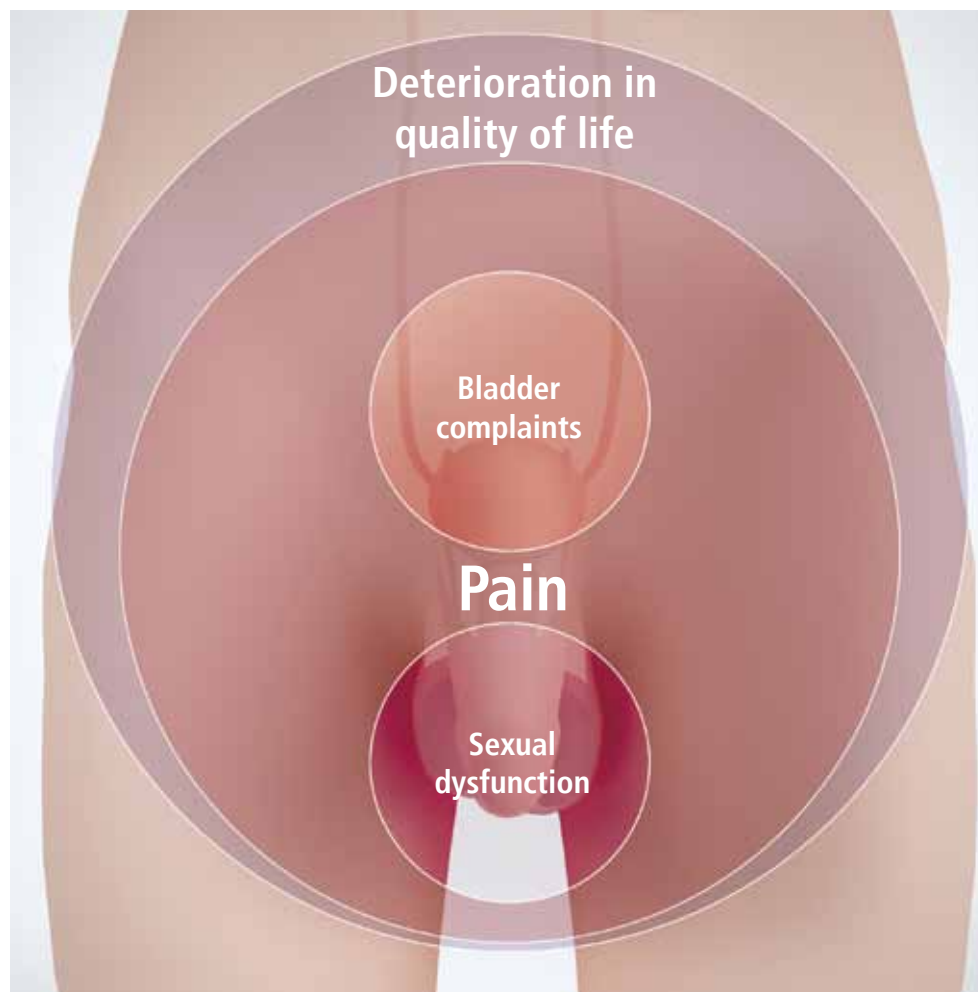
Application area »CPPS«

Chronic Pelvic Pain Syndrome

»Prostatitis« is one of the most frequent disorders to be diagnosed in routine urological outpatient practice. In the majority of cases, the patient is not suffering from a bacterial illness, but from »chronic abacterial prostatitis« or Chronic Pelvic Pain Syndrome, (CPPS, classification 3A/B in accordance with EAU guidelines). The quality of life of sufferers can be hugely restricted. The degree of suffering of patients with chronic prostatitis is comparable to those suffering from heart attacks, angina pectoris and morbus crohn. All traditional therapy options have only shown a small degree of effectiveness or none at all. The origins of the disease are still not entirely clear. Studies on genesis and therapy are sparse, with there being virtually no evidence-based studies in existence.

CPPS symptoms

- ▶ Pain
 - lower abdomen
 - pelvic floor
 - buttocks
 - anus
 - testicles
- ▶ bladder complaints
 - frequent need to pass water
 - voiding disorders
- ▶ Sexual dysfunctions
 - erectile dysfunction
 - lowering of the libido
- ▶ Deterioration in quality of life



Application area »CPPS«

Recommended treatment

Preparation

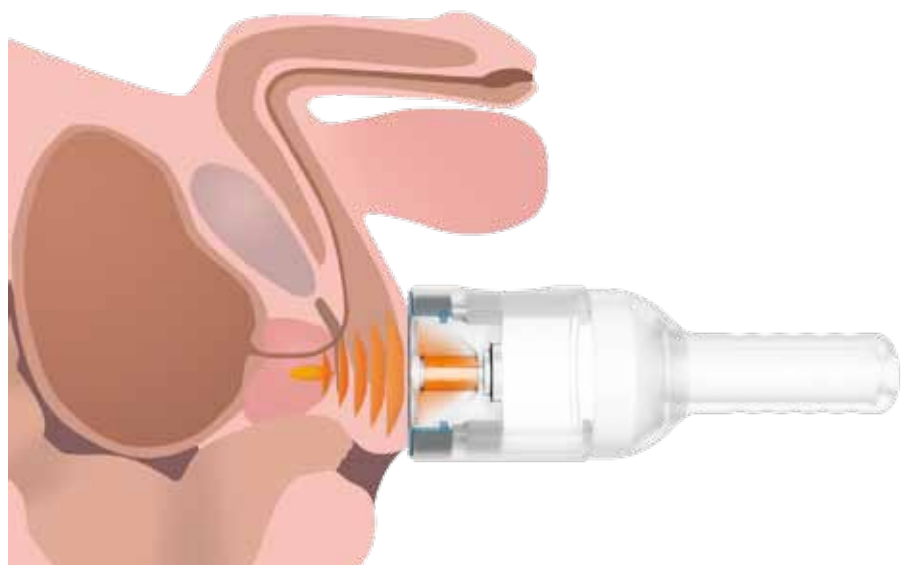
- ▶ Attach a freely movable articulated arm
- ▶ Support the patient in supine position
- ▶ No anaesthesia necessary

Application

Number:	4 treatments (1 per week)
F-SW energy density:	0.25 mJ/mm ²
Frequency:	3 – 4 Hz
Impulses/treatment:	3000 (duration approx. 15 minutes)
Stand-off:	Without
Treatment area:	Perineal application

Remarks

Position change of handpiece recommended after 500 impulses (in an area of 3 – 4 cm²), in order to treat the entire prostate region.



Application area »CPPS«

Clinical study results

Up until now, this new treatment option has been evaluated in different studies - including a prospective, randomised and placebo-controlled study^{2,3}.

The placebo-controlled study showed a significant statistical improvement in

- ▶ pain
- ▶ urination conditions
- ▶ erectile function
- ▶ and thus quality of life

of the treatment group (30 patients) in contrast to the placebo group (30 patients).

ESWT can be regarded as one of the few placebo-controlled therapy options for the straightforward treatment of CPPS with proven effectiveness. It is a fast and, hence, economically efficient outpatient therapy option, requiring little time or personnel commitments.

Advantages for the patient

The advantages of Extracorporeal Shockwave Therapy are due to the non-invasive nature of the outpatient treatment, which is simple and unproblematic to administer. It is painless and free of side effects, and can in principle be repeated as often as needed. Also, no anaesthesia is required for the treatment. ESWT cannot be used if the patient is suffering from:

- ▶ coagulation disorders (haemophilia)
- ▶ use of anticoagulants, especially Macular
- ▶ thrombosis
- ▶ tumour diseases, carcinoma patients (for tumours lying near the treatment area)
- ▶ cortisone therapy up to 6 weeks before first treatment

² R. Zimmermann et al., Extracorporeal shock-wave therapy for treating chronic pelvic pain syndrome: a feasibility study and first clinical results. *BJU Int* 2008; 102:976 – 80

³ R. Zimmermann et al., Shock Wave Therapy for the Treatment of Chronic Pelvic Pain Syndrome in Males: A Randomised, Double-Blind, Placebo-Controlled Study, *European Urology*, September 2009 (Vol. 56, Issue 3, 418 – 424)

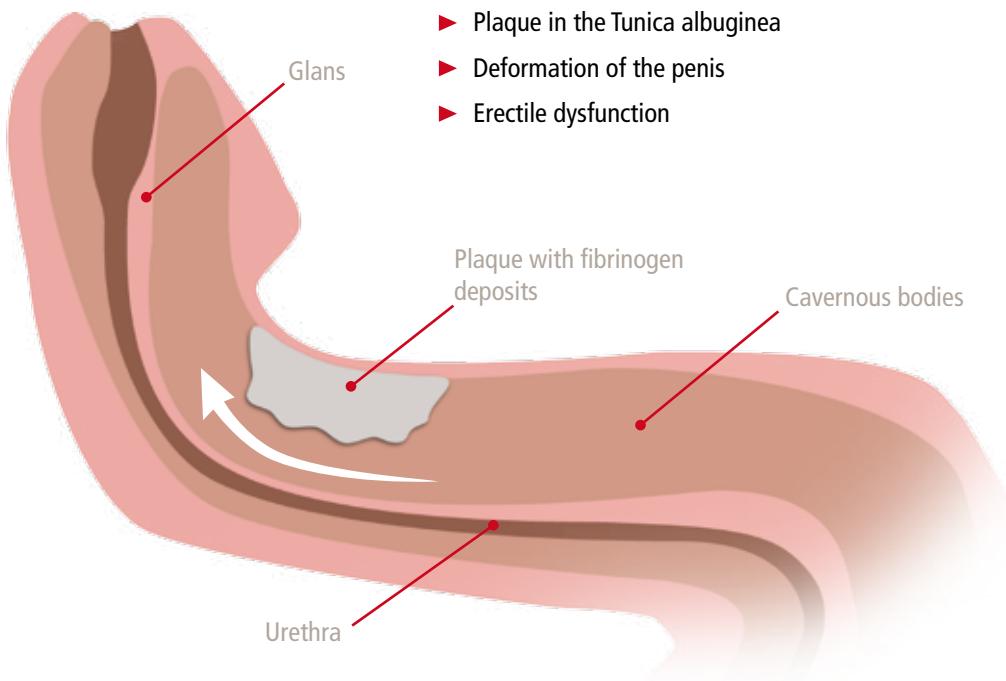
Application area »IPP«

Induratio Penis Plastica

The occurrence of Induratio Penis Plastica in the industrialised countries is on the rise with an incidence rate of 1 – 5%, and even being as high as 12% according to some literature. Middle-aged men in particular suffer from the effects of this disease, the pathogenesis of which is still unknown. Although no threatening effects are to be expected, IPP often has a huge impact on the quality of life of the men suffering from this, especially as it can lead to erectile dysfunction^{4, 5}.

IPP symptoms

- ▶ Pain in the penis
- ▶ Plaque in the Tunica albuginea
- ▶ Deformation of the penis
- ▶ Erectile dysfunction



⁴R. Zimmermann, Pathophysiologie der Induratio Penis Plastica (IPP): aktueller Kenntnisstand, J Urol Urogynäkol 15(2), 2008

⁵S. Lahme, Peyronie's Disease, UNI-MED, 2005

Application area »IPP«

Recommended treatment

Preparation

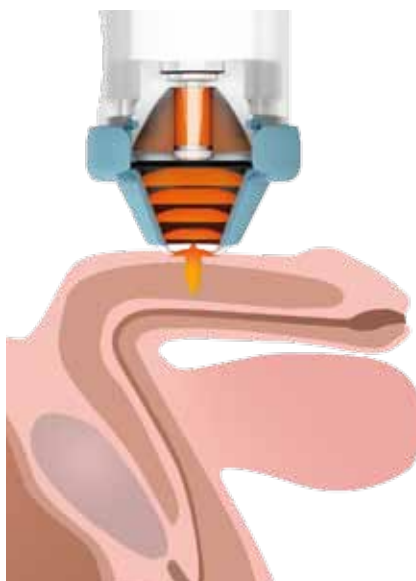
- ▶ Attach a freely movable articulated arm
- ▶ Support the patient in supine position
- ▶ Position the penis on a penis holder, which is optionally available
- ▶ No anaesthesia necessary

Application

Number:	4 treatments (1 per week)
F-SW energy density:	0.25 mJ/mm ²
Frequency:	3 – 4 Hz
Impulses/treatment:	3000 (duration approx. 15 minutes)
Stand-off:	II
Treatment area:	Palpable plaque areas of the penis

Remarks

Position change of the handpiece recommended after 500 impulses



Application area »IPP«

Clinical study results

After the first description of ESWT in patients with IPP by Bellofronte et al. in the year 1989, this therapy increasingly found its way into the clinical domain. In the majority of cases documented in the clinical studies on IPP, patients report a significant reduction in the pain symptomatology, with some patients even becoming completely free of pain^{6, 7, 8}. The first double-blind, placebo-controlled study confirmed this effect of the treatment⁹.

Along with a significant statistical improvement in

- ▶ pain sensitivity

there are also reports of improvements in

- ▶ quality of life and erectile function

as well as a stabilisation in the advancement of

- ▶ plaque formation and penis curvature

Advantages for the patient

The advantages of Extracorporeal Shockwave Therapy are due to the non-invasive nature of the outpatient treatment, which is simple and unproblematic to administer. It is painless and free of side effects, and can thus be repeated as often as needed. Also, no anaesthesia is required for the treatment. ESWT cannot be used if the patient is suffering from:

- ▶ coagulation disorders (haemophilia)
- ▶ use of anticoagulants, especially Macular
- ▶ thrombosis
- ▶ tumour diseases, carcinoma patients (for tumours lying near the treatment area)
- ▶ cortisone therapy up to 6 weeks before first treatment

⁶ M. Butz, Treatment of Peyronie's disease by extracorporeal shock wave (ESW): J Endourol 1995;5 (Suppl); 165

⁷ D. Fahlenkamp et al., Four year experience with 141 patients in one center. Scand J Urol Nephrol 2001; 5 Suppl: 20-21

⁸ S. Michel et al., 18 Month follow-up after extracorporeal shock wave treatment for Peyronie's disease: J Urol 2001;165 (Suppl): 202

⁹ A. Palmieri et al., A First Prospective, Randomized, Double-Blind, Placebo-Controlled Clinical Trial Evaluating Extracorporeal Shock Wave Therapy (ESWT) for the Treatment of Peyronie's Disease (PD), European Urology, August 2009 (Vol. 56. Issue 2, 363 – 370)

Global presence

Worldwide sales and service

Based in Tägerwil on the Swiss side of Lake Constance, the company operates around the globe through its branch offices and partners, making sure that qualified service personnel is always near at hand.



Creating synergies

The customer is the focus of everything we do!

Complex technology is only as good as the skills of the people who use it. Our training concepts are geared to the interaction between doctors, systems and patients. We offer regular seminars and workshops and provide on-the-spot training to our medical partners to ensure efficient use and operation of our systems right from the very start.

Quality

Our products are designed to satisfy all requirements in terms of quality, safety, ease of use and service life.

HUMANE TECHNOLOGY – TECHNOLOGY FOR PEOPLE



STORZ MEDICAL

STORZ MEDICAL AG · LOHSTAMPFESTRASSE 8 · CH-8274 TÄGERWILEN
TEL. +41 (0)71 677 45 45 · FAX +41 (0)71 677 45 05
E-MAIL MAIL@STORZMEDICAL.COM · WWW.STORZMEDICAL.COM