



the
art of
shock
wave

DUOLITH® SD1 T-TOP »ultra«
SHOCK WAVE TREATMENT FOR
ERECTILE DYSFUNCTION AND
UROLOGICAL PAIN THERAPY



STORZ MEDICAL



»Our passion is to communicate with one another.
Our approach is to combine sophisticated
design with functionality.«

Gerold Heine
Dr. Gerold Heine, CEO STORZ MEDICAL AG

About STORZ MEDICAL AG

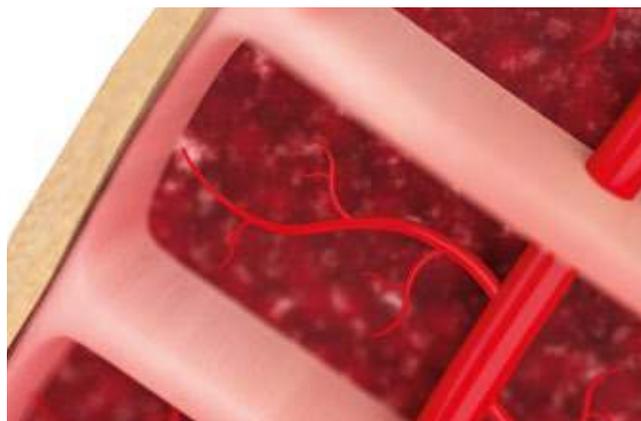
Established in 1987, STORZ MEDICAL AG is an independent partner company of the KARL STORZ Group. The aim of our physicists and engineers is the continuing research of shock wave technology, the development of new system concepts and the opening up of new indications in close co-operation with leading medical institutes.

Our products have already proven themselves in urology in millions of cases, and the advantages of the non-invasive technology have also been extended to other medical disciplines. Unique pioneering work, such as the invention of the electromagnetic cylindrical source, forms the basis for STORZ MEDICAL's broad range of activities in the field of shock wave technology.

What are shock waves?

Shock waves are audible high-energy sound waves. In the medical world, shock waves have been used successfully for the treatment of various medical conditions since around 1980. Originally only used for the disintegration of kidney stones, shock wave therapy has evolved into a recognized treatment modality in orthopaedics, cardiology and since 2010 for the treatment for erectile dysfunction (ED) of vascular origin. Shock wave therapy is a non-invasive treatment option. This means that the shock waves are generated outside of the body (extracorporeally) in a therapy system and then travel through the patient's skin into the tissue. Depending on the indication, low-energy (soft tissue treatment) or high-energy (lithotripsy) shock waves are applied.

Extracorporeal shock wave therapy initiates angiogenesis



Shock waves not only stimulate blood circulation, but they also induce the formation of new capillary blood vessels (angiogenesis). Most importantly, shock waves enhance the release of eNOS (endothelial nitric oxide synthase) and VEGF (vascular endothelial growth factor).

Electromagnetic shock wave generation delivered by STORZ MEDICAL's DUOLITH® SD1 T-TOP »ultra« is based on the physical principle of electromagnetic induction using cylindrical coil deflecting a membrane with focusing by means of rotation paraboloid. Electromagnetic shock wave generators enable precise application and gentle dosing of the shock wave energy.





STORZ MEDICAL

T-TOP

FSW ultra

ESW ultra 501

Urlogi Patients Visual Analogue Scale

Energy	0.15
Frequency	1500
Intensity	4.0
Mode	0
Charge	0.000

UrlogiSystem

DUOLITH® SD1 T-TOP »ultra« – The New Focused Shock Wave Generation

High-quality workmanship and optimal ergonomics mark the design of the new focused shock wave generation with the SEPIA® handpiece. The special flexibility of the handpiece cable supports effortless and, thus, easier treatment always directly at the patient – an important factor in the day-to-day work.

The SEPIA® handpiece renders the treatment with focused shock waves easy and efficient. All the important control elements have been inte-

grated into the handpiece. Frequency and energy level can be adjusted directly at the handpiece.

An advantage for users: The SEPIA® handpiece is compatible with all DUOLITH® SD1 »ultra« systems available. Users benefit from reduced revision costs thanks to the easy change of the coil.

Highlights

- Effective and effortless treatment directly at the patient
- All control elements integrated into the handpiece
- Reduced revision costs thanks to easy change of coil
- Focal zone depth: 0 – 65 mm
- Therapeutic effectiveness: up to 125 mm penetration depth
- Upgradable to DUOLITH® SD1 TOWER »ultra« by modular extensions

Focused SEPIA® handpiece with anatomically shaped stand-off



Handpiece display – integrated control elements



DUOLITH® SD1 TOWER »ultra«



F-SW

- 0.15 +
Energy (mJ/mm²)

- 1500 +
Shocks

- 4.0 +
Frequency (Hz)

0
Total shocks

0.000
Total energy (J)

Urology

Patients

Visual Analogue Scale



Urogenitalsystem ▶



2018/07/10 12:30
Urologic Clinic

90%



Settings

Info

Visible Body



Touch screen – The ideal extension for the DUOLITH® SD1 T-TOP »ultra«

The optional 10" touch screen is connected with a USB cable to the DUOLITH® SD1 »ultra« and expand it with valuable features: Functions and indications can be selected and accepted by tapping on the screen.

The software includes a retrievable patient management system as well as treatment parameters recommended by experienced users and supported by videos and images.

The integrated Visible Body software allows the user to immerse deeply into the muscular structures and additionally also in the macroscopic and microscopic levels of the human body. Detailed definitions and information about the human anatomy support the user. Freely moveable and rotatable 3D models allows the visualization anatomies and pathologies. Thus, a novel interaction between practitioner and patient will be enable.

Highlights

- 10" touch screen monitor (optional)
- Patient management system with treatment history
- Treatment parameters supported by videos and images
- New Visible Body® - Digital Human Anatomy Atlas: macroscopic and microscopic 3D models of the human anatomy

Treatment parameters with images



Visible Body® - Digital Human Anatomy Atlas



Application videos





DUOLITH® SD1 T-TOP »ultra«: shock wave treatment for erectile dysfunction (ED)* and urological pain therapy

The DUOLITH® SD1 T-TOP »ultra« is a shock wave therapy system for the treatment of erectile dysfunction (ED) of vascular origin, induratio penis plastica (IPP) and chronic pelvic pain syndrome (CPPS). Scientific studies have proven the efficacy of focused shock waves for these indications.^{1,2,4,5,6}

The effectiveness of the DUOLITH® SD1 T-TOP »ultra« is determined by the individually selectable, high dynamic and optimal energy range

and the adjustable therapeutic depth of focus. Deep-lying areas can be treated easily. With its optimal focus zone, it is easy to access these areas with a high degree of accuracy. These technical features also demonstrate the superiority of the treatment. Due to the depth of focus, shock waves only can be applied from one side of the penis during treatment. Another highlight is the focused handpiece SEPIA® with its anatomically shaped stand-off for a perfect adaptation to the anatomy of the penis (for treatment of ED or IPP).

Indications

- ED – Erectile dysfunction
- IPP – Induratio penis plastica (Peyronie's disease)
- CPPS – Chronic pelvic pain syndrome

Benefits

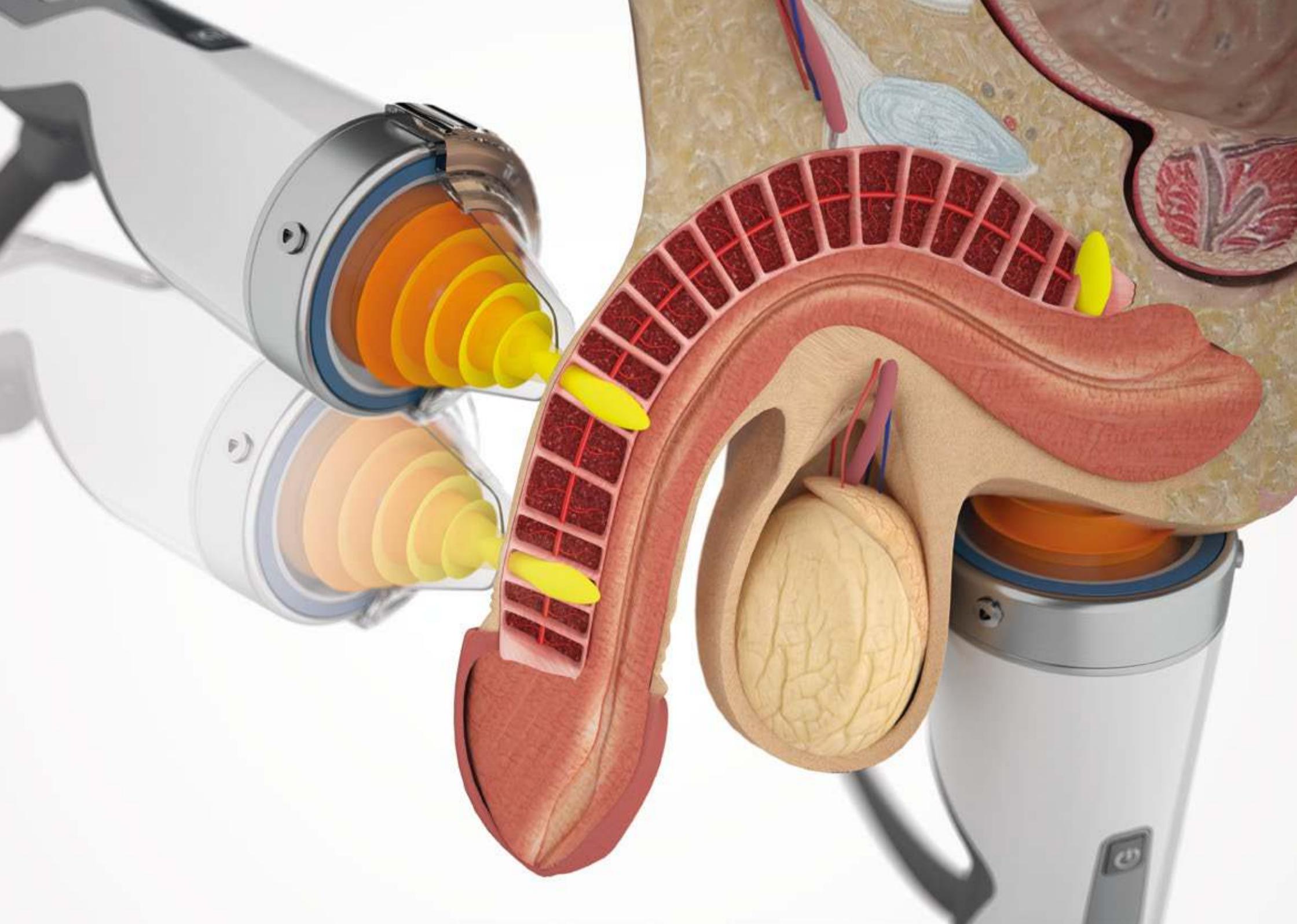
- Proven clinical results
- Non-invasive therapy
- Short treatment session
- No anaesthesia required

Milad Hanna, M.B., B.Ch. FRCS
(Ed) FRCS (Glas)
Charing Cross Hospital,
Imperial College Healthcare
NHS Trust
London
United Kingdom



“Erectile dysfunction is a common disorder of men that increases with age and may profoundly affect their quality of life. Low-intensity shock wave therapy has been proven to be effective treatment for erectile dysfunction. We use the DUOLITH® SD1 to treat patients with vascular erectile dysfunction with a good success.”

*according to Dr Hanna



Erectile dysfunction (ED) treatment with shock waves

Erectile dysfunction (ED) is a common sexual disorder. It can be defined as the inability to achieve and/or maintain an erection sufficient for satisfactory sexual intercourse. This can have a negative effect on the quality of life of men and their partners. While most often associated with older men, ED affects a significant proportion of men, starting in middle age.

Extracorporeal shock wave therapy has been used for the treatment for erectile dysfunction (ED) of vascular origin for almost a decade. When treating ED with shock wave therapy, low-intensity shock waves are applied to different treatment zones on the penis and on the perineum (crura).

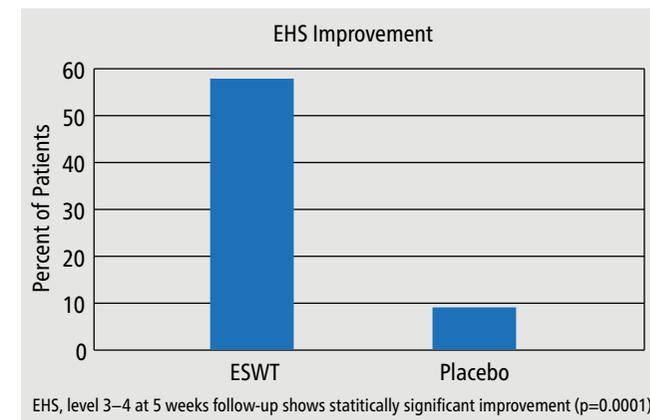
Several studies have investigated the effectiveness of low-intensity extracorporeal shock wave therapy (LiESWT) on ED. Several systematic reviews, which are the highest level of evidence according to the Oxford Centre for Evidence-based Medicine, concluded that LiESWT improves ED measured by the International Index of Erectile Function (IIEF) and Erection Hardness Score (EHS).^{7,10,11,12} A systematic review over 14 studies including 833 patients stated that LiESWT «may have the potential to be the first-choice noninvasive treatment for patients with ED».⁷ A prospective, randomized, double-blind, placebo-controlled trial¹ from 2014 showed that 57% of the men who were treated with LiESWT were able to obtain an erection after treatment and to

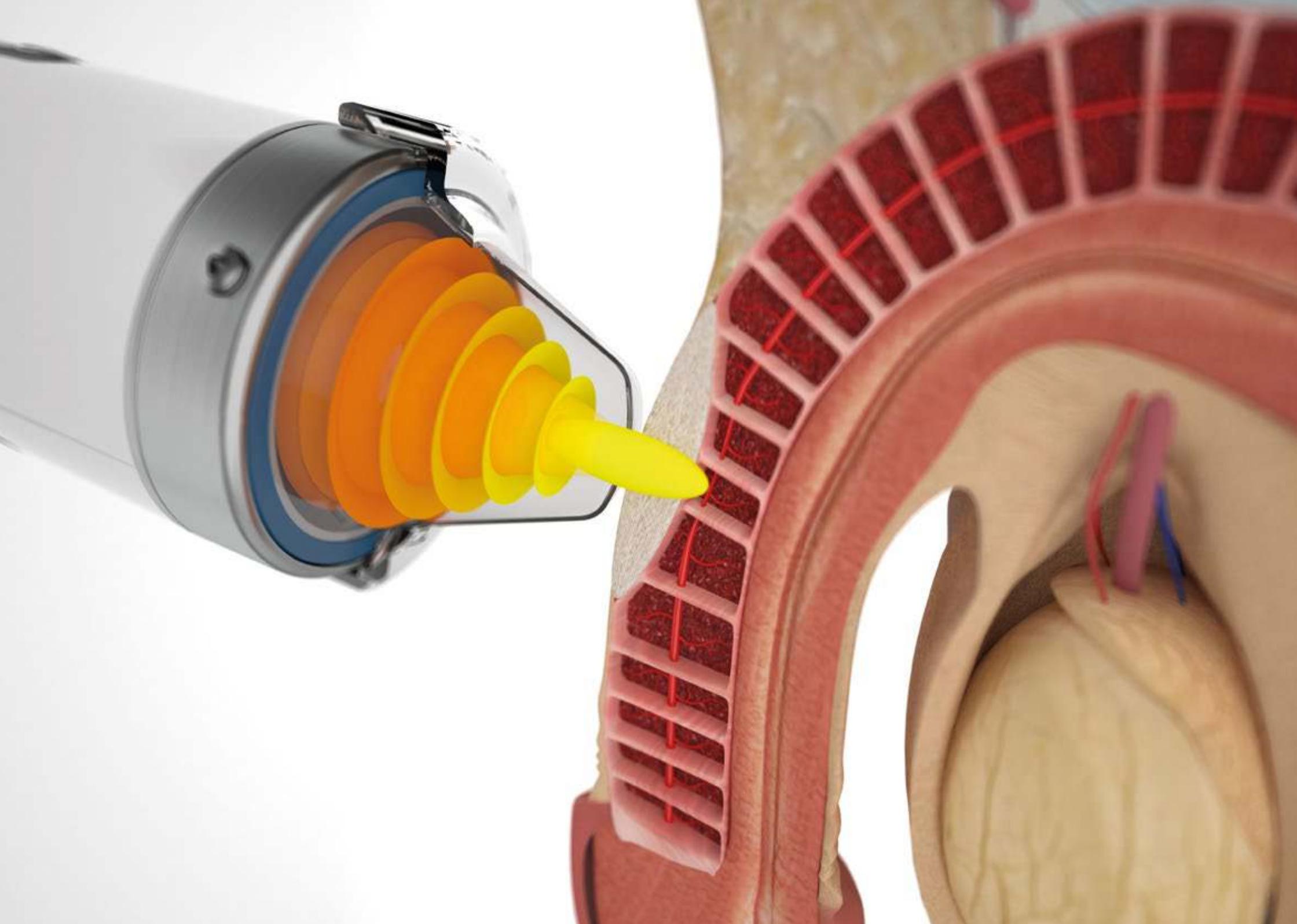
have sexual intercourse without the use of medication. An Australian study² from 2015 investigated the efficacy, safety and patient satisfaction rate after LiESWT: Most patients reported an improvement in the IIEF-5 score by 5 points (60%) and in the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) score by > 50% (70%). Most patients were satisfied (scoring 4 out of 5; 67%) and would recommend the therapy to their friends (80%). The efficacy of LiESWT has also been confirmed in animal models, for example in a study⁸ published in late 2017, in which rats with a diabetes mellitus-induced ED were treated with shock waves.

Associate Professor Eric Chung
AndroUrology Centre
Sexual, Urinary and
Reproductive Excellence in
Brisbane, Australia
University of Queensland,
Princess Alexandra Hospital,
Brisbane, Australia



“ The STORZ MEDICAL DUOLITH® SD1 is an effective device to treat men with erectile dysfunction with significant improvement reported in erectile function scores. In 70% of men improvement greater than 5 points on IIEF-5 erectile scores were reported. ”





Induratio penis plastica (IPP) treatment with shock waves

Induratio penis plastica (IPP), also known as Peyronie's disease, is an acquired and generally progressive condition of the penis. Most men notice the presence of the disease when they feel thickened nodules (so-called plaques) under the skin of the penis. As the disease progresses, pain may occur with or without an erection and the penis becomes curved during an erection, which can make it difficult or impossible to have sexual intercourse.

When treating IPP/Peyronie's disease, the pain points in the penis are treated with extracorporeal shock waves. In a pilot study³, shock waves

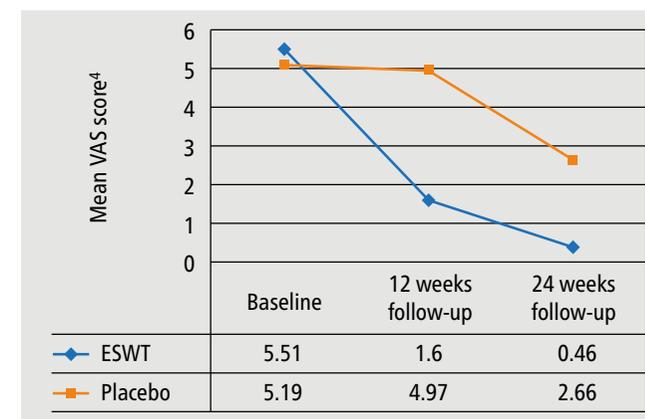
were delivered to the nonerect penis once a week for a period of five weeks. 18 months after the last shock wave session, the deviation angle had decreased from $59.3^\circ \pm 38.1^\circ$ to $49.3^\circ \pm 32.5^\circ$ ($N = 24$; $P = 0.1496$). Pain during erection disappeared in 15 of 17 patients and was reduced in one other patient ($P < 0.0001$). After shock wave treatment, 15 patients achieved satisfactory sexual intercourse (before treatment: six patients). In 2009, a clinical trial⁴ with 100 patients concluded that ESWT leads to resolution of pain and improves both erectile function and quality of life. At 12-week follow-up, mean VAS score, mean IIEF-5 score, and mean QoL score improved significantly in patients receiving

shock wave therapy. After 24 weeks, mean IIEF-5 score and mean QoL score were stable in the shock wave group, while the mean VAS score decreased even further. »Interestingly, after 24 wk, mean plaque size and mean curvature degree were significantly higher in the placebo group when compared with both baseline and ESWT values.«⁴ The authors of a systematic review⁹ published in 2017 also came to the conclusion that ESWT may resolve pain in patients with IPP/Peyronie's disease.

Lars Lund, MD, DMSci
Professor, Head of Research
Department of Urology
Odense University Hospital
and University of
Southern Denmark



“ We use the DUOLITH® SD1 to treat several andro-
logical conditions such as erectile dysfunction
(ED), chronic pelvic pain syndrome (CPPS) and
induration penis plastica (IPP). The DUOLITH® SD1
is very easy to operate and provides excellent
results. Our staff uses it daily without any prob-
lems and together with the patients they experi-
ence the treatments as safely and gently. ”





Chronic pelvic pain syndrome (CPPS) treatment with shock waves

Chronic pelvic pain syndrome (CPPS) or abacterial prostatitis is characterized by pain in the region of the pelvic floor. Further symptoms are micturition problems without evidence of urinary tract infection. Some patients experience erectile dysfunction. CPPS is found in men of any age, with the peak incidence in men aged 35 – 45 years.

Extracorporeal shock wave therapy (ESWT) is performed using a perineal approach, treating the prostate and the pelvic floor. In a study⁵ from 2009, all patients in the verum group showed statistically (highly)

significant improvement on pain, quality of life, and voiding conditions following ESWT in comparison to the placebo group. Erectile function also improved. The authors concluded that ESWT is an interesting therapy option because of its easy and inexpensive application, the lack of any side-effects, and the potential for repetition of the treatment at any time. The findings of another study⁶ from 2013 and of a systematic review⁹ from 2016 also confirmed that ESWT is a safe and effective therapy for CPPS in the short term.

¹Olsen, A. B.; Persiani, M.; Boie, S.; Hanna, M.; Lund, L.: Can low-intensity extracorporeal shockwave therapy improve erectile dysfunction? A prospective, randomized, double-blind, placebo-controlled study, *Scandinavian journal of urology*, Informa Healthcare Stockholm, 2014, 1-5.

²Chung, E.; Cartmill, R.: Evaluation of clinical efficacy, safety and patient satisfaction rate after low-intensity extracorporeal shockwave therapy for the treatment of male erectile dysfunction: an Australian first open-label single-arm prospective clinical trial, *BJU international*, Wiley Online Library, 2015, 115, 46-49.

³Michel, M. S.; Ptaschnyk, T.; Musial, A.; Braun, P.; Lenz, S. T.; Alken, P.; Köhrmann, K. U.: Objective and subjective changes in patients with Peyronie's disease after management with shockwave therapy, *Journal of endourology*, Mary Ann Liebert, Inc., 2003, 17, 41-44.

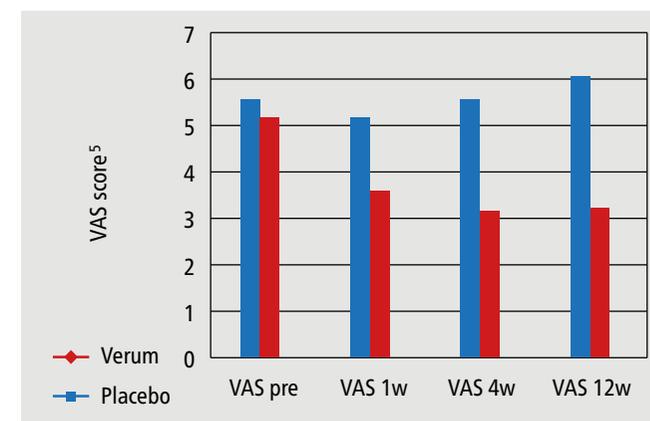
⁴Palmieri, A.; Imbimbo, C.; Longo, N.; Fusco, F.; Verze, P.; Mangiapia, F.; Creta, M.; Mirone, V.: A first prospective, randomized, double-blind, placebo-controlled clinical trial evaluating extracorporeal shock wave therapy for the treatment of Peyronie's disease. *European Urology*, Elsevier, 2009, 56(2), 363-370.

⁵Zimmermann, R.; Cumpanas, A.; Miclea, F.; Janetschek, G.: Extracorporeal shock wave therapy for the treatment of chronic pelvic pain syndrome in males: a randomised, double-blind, placebo controlled study, *European urology*, Elsevier, 2009, 56, 418-424.

⁶Vahdatpour, B.; Alizadeh, F.; Moayednia, A.; Emadi, M.; Khorami, M. H.; Haghdani, S.: Efficacy of Extracorporeal Shock Wave Therapy for the Treatment of Chronic Pelvic Pain Syndrome: A Randomized, Controlled Trial, *ISRN urology*, Hindawi Publishing Corporation, 2013, 2013, 1-6.

⁷Lu, Z.; Lin, G.; Reed-Maldonado, A.; Wang, C.; Lee, Y.C.; Lue, T.F.: Low-intensity Extracorporeal Shock Wave Treatment Improves Erectile Function: A Systematic Review and Meta-analysis, *European Urology*, 2016, 71(2), 223-233.

⁸Jeong, H.C.; Jeon, S.H.; Qun, Z.G.; Kim K.S.; Choi, S.W.; Bashraheel, F.; Bae, W.J.; Kim, S.J.; Cho, H.J.; Ha, U.S.; Hong, S.H.; Lee, J.Y.; Moon, D.G.; Kim, S.W.: Effects of Next-Generation Low-Energy Extracorporeal Shockwave Therapy on Erectile Dysfunction in an Animal Model of Diabetes, *World J Mens Health*, 2017, Dec; 35(3):186-195.



⁹Fojecki, G. L.; Tiessen, S.; Osther, P.J.S.: Extracorporeal shock wave therapy (ESWT) in urology: a systematic review of outcome in Peyronie's disease, erectile dysfunction and chronic pelvic pain, *World Journal of Urology*, 2017, 35(1), 1-9.

¹⁰Clavijo, R. I.; Kohn, T. P.; Kohn, J. R. & Ramasamy, R.: Effects of Low-Intensity Extracorporeal Shockwave Therapy on Erectile Dysfunction: A Systematic Review and Meta-Analysis, *The journal of sexual medicine*, 2017, 14, 27-35

¹¹Man, L. & Li, G.: Low-Intensity Extracorporeal Shock Wave Therapy for Erectile Dysfunction: a Systematic Review and Meta-Analysis., *Urology*, 2017

¹²Angulo, J. C.; Arance, I.; de Las Heras, M. M.; Meilán, E.; Esquinas, C. & Andrés, E. M.: Efficacy of low-intensity shock wave therapy for erectile dysfunction: A systematic review and meta-analysis. *Actas urologicas espanolas*, 2017, 41, 479-490



www.storzmedical.com



HUMANE TECHNOLOGY – TECHNOLOGY FOR PEOPLE



Urology Orthopaedics Cardiology Aesthetics Dermatology Neurology Veterinary

STORZ MEDICAL

STORZ MEDICAL AG · Lohstampfstrasse 8 · 8274 Tägerwilten · Switzerland
Tel. +41 (0)71 677 45 45 · Fax +41 (0)71 677 45 05 · info@storzmedical.com · www.storzmedical.com

Subject to change without notice. The information in this brochure is only intended for medical and healthcare professionals. This brochure provides information on products/indications that may not be available/relevant in all countries. The products listed below and referred to in this brochure are provided by our technology partners to complete the DUOLITH® »ultra«: Visible Body®

