

**LINEAR FOCUSED PIEZO SHOCKWAVES  
TO TREAT  
ERECTILE DYSFUNCTION**



**ESWT-ED**

# EXTRACORPOREAL SHOCKWAVE- THERAPY TO TREAT ED

## Disclaimer

ELvation Medical GmbH and Richard Wolf GmbH have taken the greatest care when compiling this brochure. Nevertheless, it is impossible to completely exclude all mistakes. None of the information and recommendations in this brochure can be construed as a basis for any claims against ELvation Medical GmbH or Richard Wolf GmbH. Any liability based on statutory regulations is limited to liability for gross negligence or intent. 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 is related to the treatment of Erectile Dysfunction.

The information in this brochure is not intended as a replacement for the information provided by the most current User Manuals of the different shockwave systems. Depending on the individual circumstances it may be necessary to deviate from the values and settings given in this brochure. Medical knowledge is constantly subject to change as a consequence of new research and clinical developments. This means that it may be necessary to deviate from the information provided in this brochure.

## Basic principles of extracorporeal shockwave therapy (ESWT)

Extracorporeal shockwave therapy (ESWT) for erectile dysfunction (ED) is a non-invasive procedure to treat vasculogenic ED. A shockwave is a strong, expansive, acoustic pressure wave with an extremely short rise time of just a few nanoseconds, which is followed after a few microseconds by a brief moment of negative pressure, after which pressure returns to normal again. The focused shockwaves used in ESWT reach their highest point of pressure precisely in the target tissue.

For a long time the biological mode of action of shockwaves was not understood; recently, the effects have been described very precisely. Research results have been confirmed by clinical experiences reporting significant improvements in many indication fields like orthopaedics, wound-healing and ED.

## Evolution of ESWT

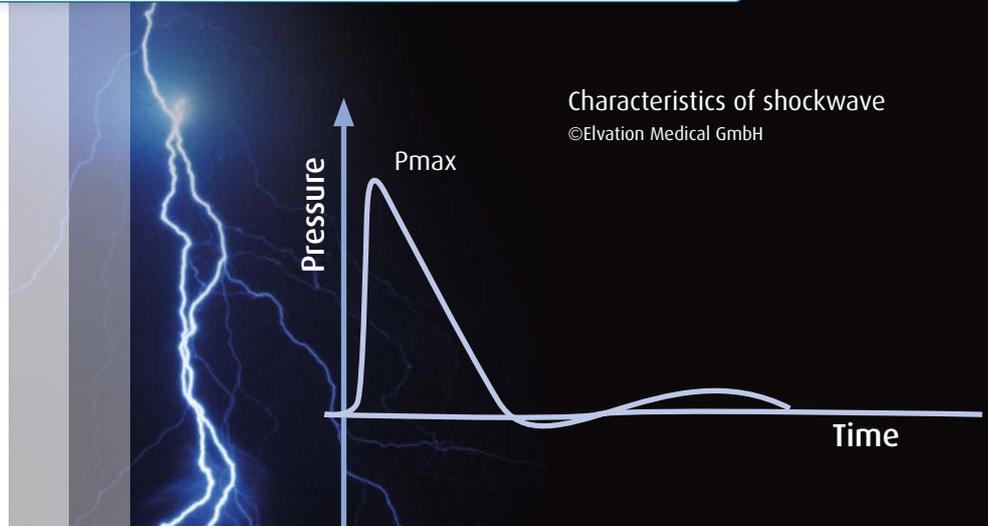
ESWT developed out of the technology used for extracorporeal shockwave lithotripsy (ESWL) which utilizes acoustic shockwaves to break up kidney stones. Over time, as several hundred thousand patients were treated, special systems were developed to use shockwaves to treat the musculoskeletal system. Initially used to treat pseudarthrosis, ESWT established itself as one of several applications used by physicians for conservative treatment. Today, ESWT is being suggested for use in a range of new applications which include treating vasculogenic erectile dysfunction.



**PiezoWave<sup>2</sup>**

## Physical principles of acoustic shockwaves

Acoustic shockwaves are characterized by a strong acoustic pulse with spatial expansion and a very short rise time of only a few nanoseconds. After a few microseconds the rise is followed by a brief period of negative pressure, after which pressure returns to normal again.

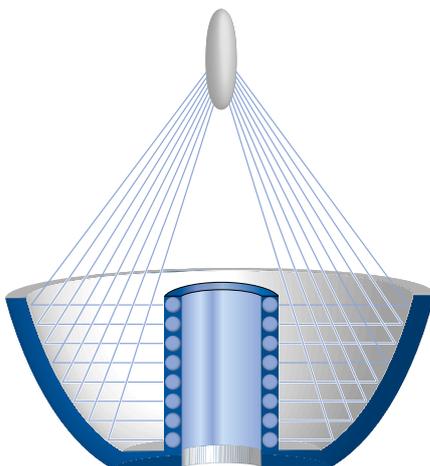


## shockwave technologies

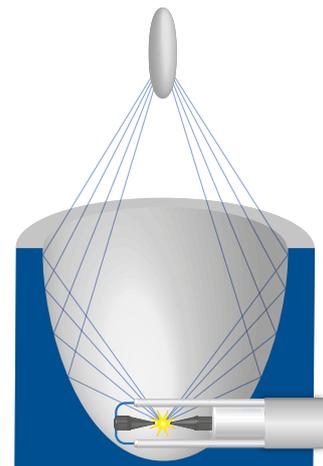
There are a number of focused shockwave systems on the market, all of which are based on one of the three basic shockwave technologies listed below:

- electrohydraulic shockwaves
- electromagnetic shockwaves
- piezoelectric shockwaves (such as the PiezoWave, WellWave and PiezoSon of Richard Wolf GmbH)

Piezoelectric, electromagnetic and electrohydraulic shockwave technologies all create shockwaves suitable for focused ESWT. They differ from one another in the manner in which the shockwaves are generated and in the characteristics of the created shockwaves such as volume of noise, focal size, durability of the therapy source, adjustment and focusing of the shockwave, etc. Electrohydraulic systems use a spark discharge to generate shockwaves and a reflector to focus the acoustic shockwaves. Electromagnetic shockwave systems are similar but use an electromagnetic coil to generate shockwaves rather than a spark discharge



Elektromagnetische Stoßwelle

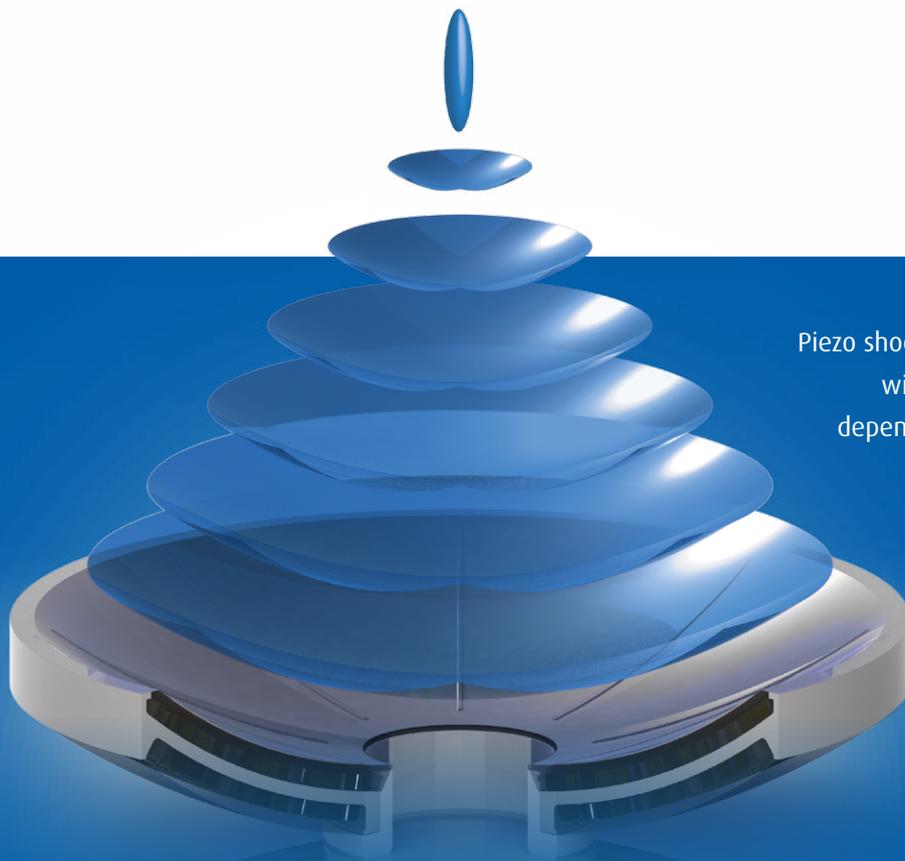


Elektrohydraulische Stoßwelle

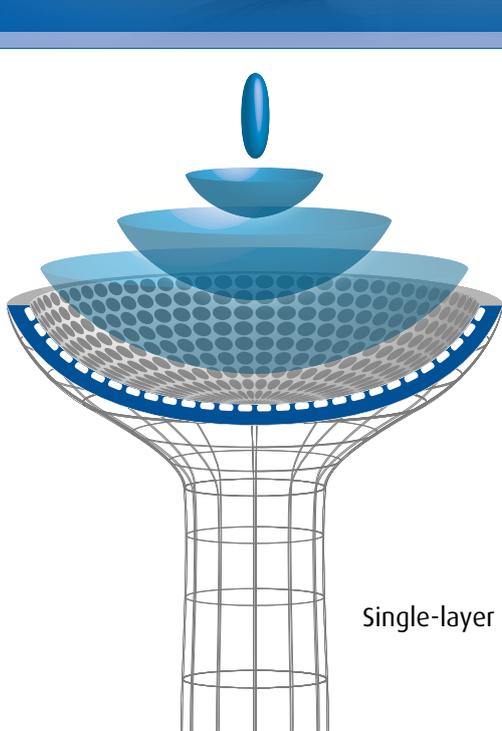
## The piezoelectric principle: superior and focused

Piezoelectric shockwaves are an improvement on the classic electromagnetic and electrohydraulic means of generating shockwaves. Piezo ceramic crystals are arranged on a concave transducer in a mosaic pattern. A high-voltage current briefly excites the piezo crystals, causing them to expand simultaneously a few micrometers along their axis to create a pressure wave. The piezo elements are aligned precisely to the therapy focus. The precise, focused, and nonlinear dissemination of the pulse results in steepening at the point of focus, creating a shockwave.

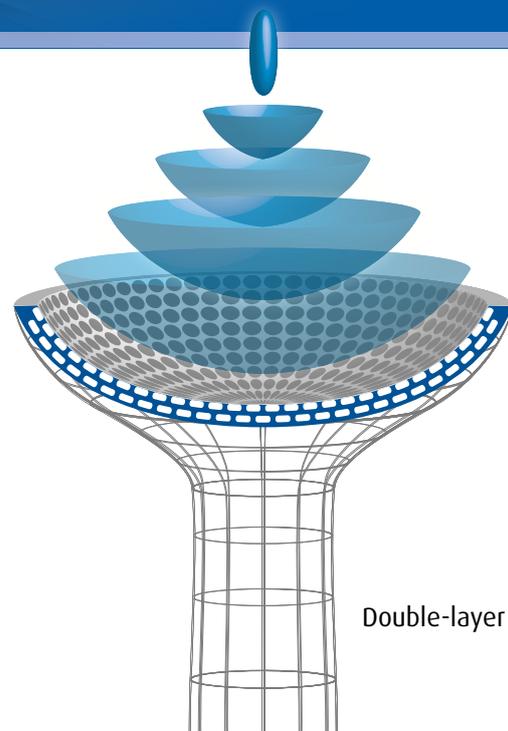
The piezo shockwave is the only shockwave which uses “direct focusing” and does not require an additional reflector. This accounts for the compactness of the therapy source and the precise, well-defined focal zone. Treatment is quiet and virtually pain-free and the technology allows intensity levels to be freely adjusted with almost no impact on focal size. Piezo shockwave technology is extraordinarily durable.



Piezo shockwave therapy sources are available with single or double-layer technology, depending on the intensity levels required.



Single-layer technology

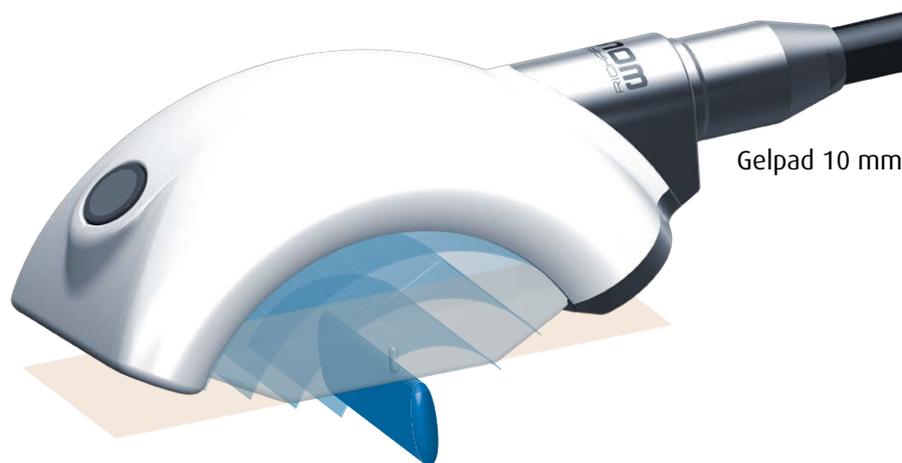
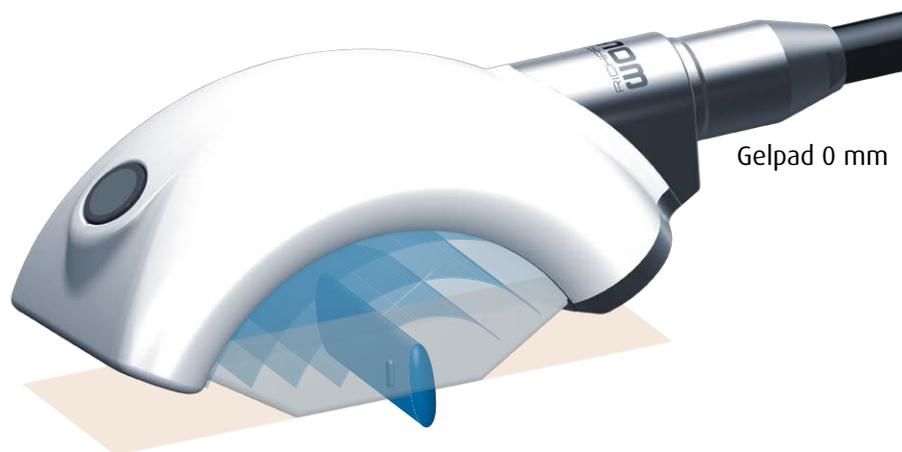


Double-layer technology

## Unique for the treatment of vasculogenic ED: The piezo-shockwave with a linear therapy focus

Richard Wolf GmbH and ELvation have developed a new and unique technology: a linear, focused shockwave. The aim was to create a shockwave that could be applied more uniformly and more effectively compared to the single pointed focus of conventional shockwaves.

Gel pads are used to adjust the penetration depth to between 0 and 20 mm and to ensure that the acoustic field is optimally adapted to long segment treatments.



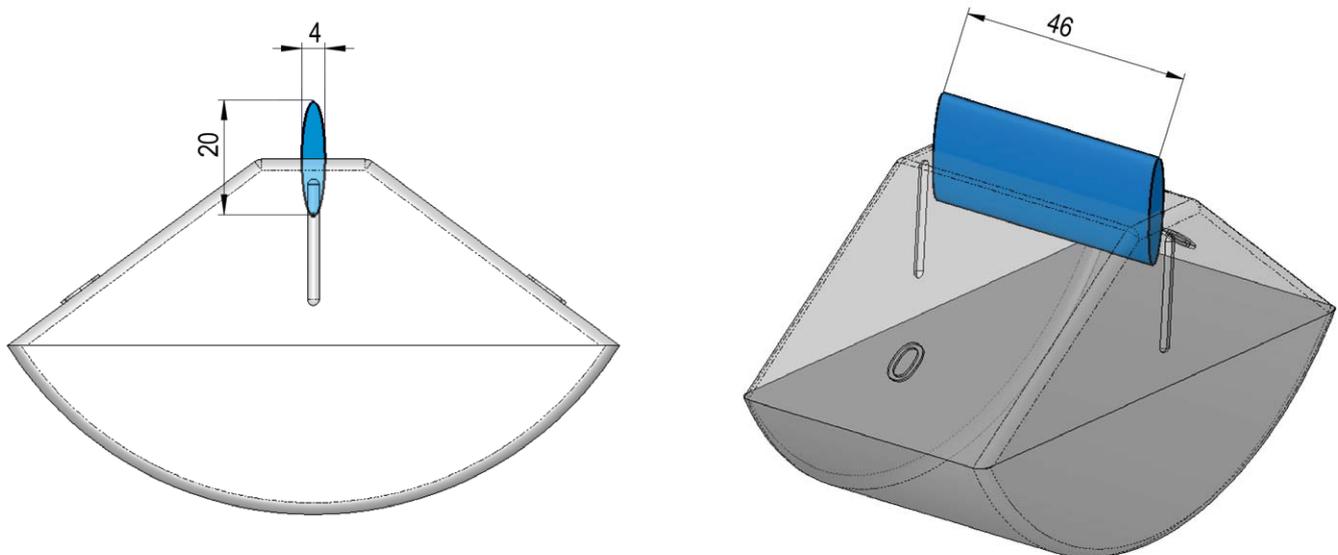
## Focal zone and penetration depth

The focal zone of a piezo shockwave is the area where the pressure waves steepen to create a high-energy shockwave and exert the maximum mechanical pressure on the tissue in that area. The area is defined in such a way that the shockwave forms precisely in the target tissue with the requisite amount of energy but with only minimal trauma to surrounding tissue.

The focal zone of a linear, focused, piezo source (FBL 10x5 G2, intensity 10) has an area of 46 mm x 20 mm x 4 mm. The "direct focusing" technology of the piezo shockwave system means that the size of the focal area barely changes even when the intensity settings are changed.

The penetration depth of the focal zone is pre-selected using gel pads of different thicknesses. A special feature of linear, focused shockwaves is that users can also select a "0" gel pad. Half of the focal zone remains within the gel pad, ensuring that the peak pressure in the middle of the focus occurs precisely at the skin surface.

It was found that 10-20mm penetration depth worked best for ED applications.



## Intensity Settings

In the literature, the recommended intensity settings for focused shockwaves to treat ED are described as low intensity Energy-levels. In general, this includes energy flux densities of between 0 and 0.30 mJ/mm<sup>2</sup>. Experience has shown, however, that energy flux densities of maximally 0.160 mJ/mm<sup>2</sup> produce good results when treating ED. The frequency setting should be 6 Hz- 8Hz.



### Energy flux densities: therapy source FBL 10x5 G2

Level	FBL10x5G2 Energy flux density (mJ/mm <sup>2</sup> )
0,1 - 1	0,018
2	0.021
3	0.027
4	0.029
5	0.034
6	0.041
7	0.046
8	0.051
9	0.060
10	0.064
11	0.069
12	0.079
13	0.087
14	0.097
15	0.106
16	0.113
17	0.126
18	0.139
19	0.147
20	0.160

## Mechanism of action of ESWT to treat ED

In recent years, numerous scientific studies and publications, some of which also used focused piezo shockwaves, have described the mechanism of action of ESWT. In principle, ESWT is a strong, targeted, mechanical stimulus which promotes biological self-healing processes. On closer inspection, improvement of the erectile function is the result of a number of complex shockwave effects. Mechanical stimuli influence many cellular functions in living tissue, including cell growth, cell differentiation, cell migration, protein synthesis, physiological apoptosis and tissue necrosis. Extracorporeal shockwaves are mechanical stressors capable of inducing biochemical changes in living tissue, which on a molecular level ultimately affect the gene expression of cells, thereby eliciting certain tissue reactions when selectively applied. This process is referred to as mechanotransduction.

Mechanisms of action and effects of ESWT described in the literature. The increase in blood flow and neovascularization in vascular ED has surely a particular importance:

- induced release of growth factors such as TGF- $\beta$ 1, VEGF
- stimulation of fibroblast proliferation
- stimulation of local blood flow and suppression of pro-inflammatory processes
- neovascularization
- antibacterial effect
- stimulation of mesenchymal stem cell migration

## Contraindications for ESWT

In principle, ESWT is rarely contraindicated. The most recent relevant information on contraindications is given in the current ESWT Operating Manuals. The Operating Manuals for therapy sources manufactured by Richard Wolf list the following contraindications in general:

Malignant tumor diseases  
Blood clotting disorders (it may necessary to check the patient's coagulation status)  
Taking blood thinning medication  
radical prostatectomy  
penile prothesis  
etc.

ESWT systems are only approved for use by trained medical specialists and may only be operated by qualified persons who have been trained in the application of ESWT for medical purposes. The user applying the treatment must decide, based on the patient's general condition, whether a planned application should be carried out or not. For further information, please consult the recent specialist literature.

## Use of ESWT- Erectile Dysfunction

ESWT-ED is tolerated very well by patients and treatment is uncomplicated. Sedation or anesthesia is generally not required. To achieve optimal coupling for the transmission of shockwave energy to the focal zone, it is important to ensure that no air pockets are present on the surface. As in ultrasound examinations, the presence of air pockets between the therapy source and the target tissue must be avoided. Experiences showing good results treating ED with four weekly sessions, 1 time per week 6000 shocks, gel pad 10mm, Intensity 0,160 mJ/mm<sup>2</sup>.

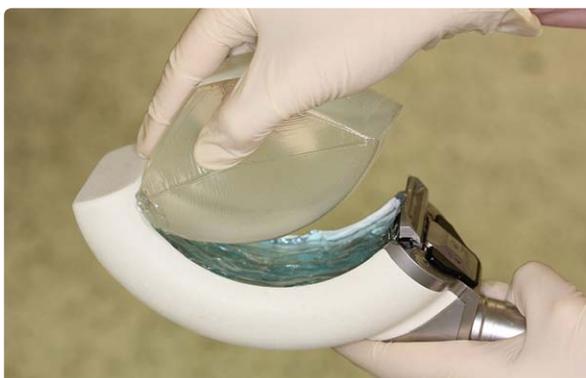
1. The therapy source must be cleaned and all gel remnants removed (at least 1x per day)
2. The therapy source must be filled with fresh ultrasound gel (at least 1x per day)
3. The gel pad must be inserted in the therapy source without any air pockets
4. Insert therapy source, switch on unit and pre-select frequency and intensity (see chapter on Intensity Settings)
5. Cleanse gel pad again if necessary (e.g. ethanol disinfectant)
6. Apply shockwave gel to the gel pad
7. 2000 shockwaves corpus cavernosum right ; 2000 shockwaves corpus cavernosum left; gel pad 10
8. 1000 shockwaves left crus; 1000 shockwaves right crus; gel pad 10-15
9. Clean gel pad after use (e.g. ethanol disinfectant)



1



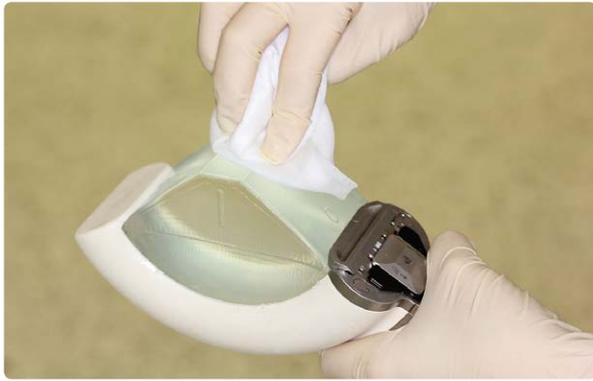
2



3



4



5



6



7



8

Energy flux density: 0,160 mJ/mm<sup>2</sup>  
Frequency: 6Hz- 8Hz  
4 x 1 treatment per Week

1000 Shocks

1000 Shocks

2000 Shocks

2000 Shocks



## service and maintenance

The piezoelectric crystals make this therapy source extremely durable. The therapy source has a guaranteed working life of 5 million pulses, a significantly longer lifespan than both electrohydraulic and electromagnetic systems.

## Piezo Technology

- Direct focusing technology
- Precisely adjustable penetration depth
- Penetration depth and intensity settings can be adjusted independently
- Linear therapy focus: perfect for uniform applications
- No pain at the interface between patient and device
- Low noise levels
- Very long lifespan
- Compact





H. G. Neuland, H. J. Duchstein. **Manifestation Pattern of the Extracorporeal Shock Wave Therapy using Mechanotransduction.** Orth.Praxis 4.2006

H. G. Neuland, A. Schmidt. **Induction of Adult (Tissue-specific) Mesenchymal Stem Cells through Extracorporeal Shock Waves to Regenerate Musculoskeletal Tissue.** Orth.Praxis 2006

Laura Berta, Annamaria Fazzari, Anna Maria Ficco, Patrizia Maurici Enrica, Maria Graziella Catalano, and Roberto Frairia. **Extracorporeal shock waves enhance normal fibroblast proliferation in vitro and activate mRNA expression for TGF- $\beta$ 1 and for collagen types I and III.** Acta Orthopaedica 2009; 80 (5): 612-617

Giuliana Muzio, PhD, Enrica Verne et al . **Shock Waves Induce Activity of Human Osteoblast-Like Cells in Bioactive Scaffolds.** The Journal of Trauma Injury, Infection, and Critical Care 2010

J. Fehre, W. Krauß, A. Lutz, R. Reitmajer, A. Tóth-Kischkat, F. Ueberle, O. Wess. **Fokussierte und unfokussierte Druck und Stoßwellen – Unterschiede und Gemeinsamkeiten Eine Abhandlung erstellt durch den wissenschaftlichen Beirat Physik / Technik der DIGEST**

Chen YJ, Wurtz T, Wang CJ, Kuo YR et al. **Recruitment of mesenchymal stem cells and expression of TGF-beta 1 and VEGF in the early stage of shock wave-promoted bone regeneration of segmental defect in rats.**J Orthop Res. 2004 May;22(3):526-34

Yan X1, Zeng B, Chai Y, Luo C, Li X. **Improvement of blood flow, expression of nitric oxide, and vascular endothelial growth factor by low-energy shockwave therapy in random-pattern skin flap model.** Ann Plast Surg. 2008 Dec;61(6):646-53. doi: 10.1097/SAP.0b013e318172ba1f.

Chi-Hang Yee, Eddie SY Chan, Simon See-Ming Hou and Chi-Fai Ng **Extracorporeal shockwave therapy in the treatment of erectile dysfunction: A prospective, randomized, double-blinded, placebo controlled study,** International Journal of Urology (2014) doi: 10.1111/iju.12506



# PiezoWave<sup>2</sup>



spirit of excellence



Elvation Medical GmbH  
Ludwig-Wolf-Str. 6  
75249 Kieselbronn-Germany  
+49 72 31 - 56 36 56 tel  
+49 72 31 - 56 36 46 fax  
info@elvation.de  
www.elvation.de

