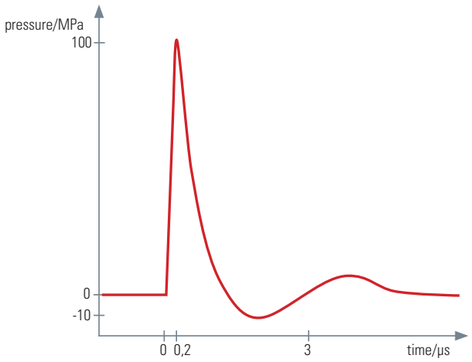
Zimmer
MedizinSystems

TREATMENT MANUAL
Focused shockwave

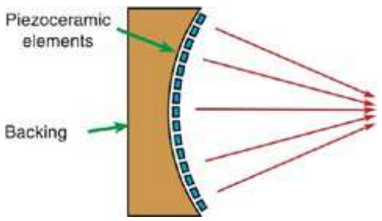
EN

ESWT

Content



Characteristic focused shockwave



Piezoceramic element (schematic view)

Shockwave therapy history

ESWT in orthopaedics, traumatology, and more recent in aesthetics is a therapeutic method that Dahmen et al in 1992 used for the first time to treat calcific tendinitis. Since then, ESWT has evolved and gained acceptance within the orthopaedic, physiotherapeutic, and aesthetics community. Today physicians have an overview of several ten thousand treated patients worldwide. Nevertheless, the healing mechanism of ESWT for treatment of the established indications like epicondylitis or heel spur is not completely understood.
For years electrohydraulic, piezoelectric and electromagnetic systems have been used for shockwave generation. Since 2000, also pneumatically or mechanically generated low- to medium-energy radial shock wave therapy (RSWT) is used.

Extracorporeal shockwaves; principle

From the physical point of view a shock wave is defined by an abrupt, nearly discontinuous change in pressure and by having a velocity that is higher than the speed of sound in the medium it propagates. Generally a shock wave can be described as a single pulse with a wide frequency range (from approx. 150 kHz up to 100 MHz), high pressure amplitude (up to 150 MPa), low tensile wave (up to -25 MPa), small pulse width and a short rise time of up to a few hundred nanoseconds.

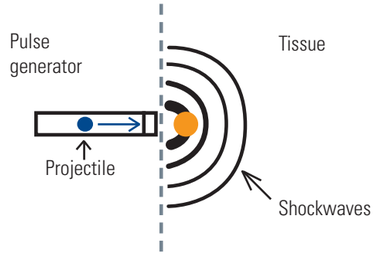
For extracorporeal shockwave therapy with a piezoelectric system, the handpiece delivers a selected number of shockwaves as generated by piezo crystals mounted in it, with a selected energy intensity and frequency.

The handpiece is applied to the patient's skin to deliver the shocks to the focus point. A silicone cap on the handpiece determines how deep the shockwaves will penetrate the body. The resulting energy or shock intensity in the focus point depends on the energy applied to the piezo crystals, the characteristics of the piezo crystals, and the geometry of the handpiece. Therefore, the intensity at the focal point of the shock wave is an important parameter and is expressed as the amount of energy applied per area (in mJ/mm^2), the so-called energy density (ED), or energy flux density (EFD). The energy density may influence the therapeutic effects of ESWT. In clinical practice, the ED levels of ESWT range from 0.001 to 0.5 mJ/mm^2. In clinical practice, often the ED level used during treatment is adjusted to just below the patient's pain tolerance limit.

Difference to radial shockwaves

In the case of Radial shockwave therapy, hereafter referred to as RSWT, an electromagnetic generator or air pressure compressor accelerates a projectile-like mass and creates these shockwaves ballistically.
With RSWT, the rise time of the pressure pulse is longer than with ESWT. The maximum pressure is around 15 MPa. The waves are transmitted to the tissue via applicators of various diameters and geometry.

During this process, the shockwaves propagate radially from the transmission point into the tissue.
They penetrate approximately 35-40 mm. And at 40 mm, the wavelength of the shockwaves is much longer than the diameter of the applicator heads as the pressure shock source, resulting in divergent, non-focused wave propagation.
The amount of energy in the shockwaves is controlled with different acceleration of the projectile.



Characteristic radial shockwave

Mechanism of action / effects

Mechanism of action / effects

The exact mechanism of action of ESWT is still under discussion. New studies are regularly carried out, which should provide more and more clarity. But increasing evidence proves that extracorporeal shockwave treatment is safe and effective for treating several musculoskeletal disorders.
The mechanism of action should be classified according to the timing and specific characteristics of an individual shock. The positive phase produces mechanical forces, whereas the negative phase generates cavitation and a second wave of shockwaves. These two principles generate, together, 3 major reaction phases.

- Physical phase, were positive pressure generates absorption, reflection, refraction and transmission of energy into tissue.
- Physicochemical phase, were biomolecules as ATP is stimulated
- Biological phase, in which focussed shockwaves modulates angiogenesis, eNos, PCNA, VEGF and anti-inflammatory effects

Based on above, studies have stated a scientific basis for the following working mechanism / effects:

- Long-term pain relief, which often occurs during or immediately after treatment
- Positive influence on an inflammatory reaction in musculoskeletal disorders
- Disruption of calcifications within tendons
- Treatment of non-union fractures and for bone healing.

In addition, ESWT promotes improved blood circulation, and after treatment there is often a vasodilatation and an increase in the production of new blood vessels. This is essential for the supply of nutrients and the removal of waste products.

Treatment with the en*Shock*

Treatment with the en*Shock*

Zimmer MedizinSysteme GmbH shockwave devices have been used for more than 15 years for patients with a wide variety of disorders. Started with the en*Puls*, quickly followed by the en*Puls 2.0* and enPuls*Pro* the radial shockwave devices consist now of the en*Puls 2.0 NG* and enPuls*Pro NG* for musculoskeletal disorders. In addition, radial shockwave devices for aesthetic and urological applications complement the range.
The en*Shock* is Zimmer MedizinSysteme GmbH first state of the art focused shockwave device, and completes the portfolio to provide a full range of devices, covering all treatable indications. Because the user interface is very similar to the en*Puls 2.0 NG*, the device is very user-friendly. Users will therefore be able to correctly operate the device quick and intuitive.

Users:
The en*Shock* is intended to be used by health care practitioners, such as physiotherapist, technicians and nurses who carefully read and understand the Instructions for Use.

Patients:
The en*Shock* should only be used on patients who are physically and mentally capable to consciously perceive and express pain stimuli. For a detailed list of contraindications and precautions, please refer to corresponding chapter on page 21.

Preparation:

- Ensure that the patient is in a safe and comfortable position. The operator must be able to easily reach the affected area.
- Make sure that between the applicator and gelpad is sufficient conductive gel.
- Make sure that a correct gelpad is used.
  The en*Shock* comes with 8 gelpads to ensure an optimal penetration depth. The diameter of the gelpads reflects the penetration depth.
  The diameter of the gelpad can be read on the gelpad in question.
- Make sure to use sufficient conductive gel between the gelpad and the patient's skin.
- Set all parameters and start the treatment by selecting the start button, immediately followed by clicking the orange button on the handpiece. (Or by pressing 'Shock' on the optional foot switch).

Note:
Prior to using the device on a patient, the user should become familiar with the instructions for use and the individual treatment methods to be used as well as the indications/contraindications, warnings and application information. Additional sources of information about the therapy should also be followed.

Gel applied to the handpiece

Gelpad with 5 and 10 mm diameter

Gel applied on the gelpad

Treatment with the en*Shock*

Note:
Not using conducting gel or using it inadequately can affect the treatment.

Note: Use only the conductive gel supplied by Zimmer MedizinSysteme GmbH.

Pinpoint trigger points

Marked trigger point and dynamic area

- Position the handpiece at right angles to the skin surface and apply its own weight.

- An acoustic signal will sound after the therapy time has elapsed.

It is recommend to create a virtual grid over the treatment area and to pinpoint trigger points by detecting the point with the greatest sensitivity.

Application methods

Static
The handpiece is applied to one point and only modulated vertically with the contact pressure. This method is used when treating localised problems.
Semi-static: the handpiece remains on the point. The affected area is also treated by moving the handpiece evenly, working outwards from the vertical position, with the amount of force applied varying according to the direction. This method is used to treat localised, but painfull problems.

Dynamic
The handpiece is moved with the head in-situ and by applying contact pressure over the structure to be treated, without interrupting the pulse sequence. This method is used to treat larger areas.

Combination
Often a combination of static (or semi-static) and dynamic will be applied to achieve maximum results.

Combination radial and focussed shockwave
The results of treatment with either radial or fokussed shockwave are convincing, if given to the right indication.

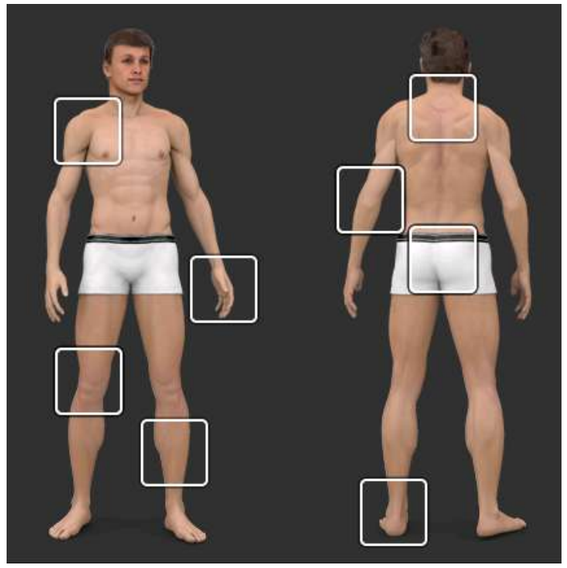
When the specific advantages of both modalities are taken into account, scientists and specialists conclude that a combination of focused and radial shockwaves produces better results.

Indications

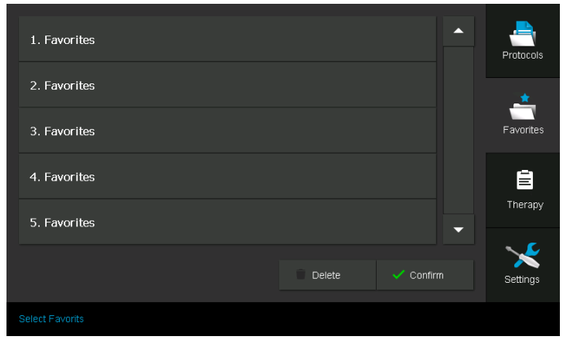
Indications

The en*Shock* provides focused shockwave therapy for people with musculoskeletal disorders and other conditions as considered appropriate by the health care professionals providing treatment.

The en*Shock* is indicated for:
- Myofascial trigger points and the effects they have on back pain, neck pain and myofascial pain syndrome
- Calcifying tendinitis of the shoulder and calcifying tendinopathy, calcific tendinitis and rotator cuff disease with or without calcification
- Subacromial pain syndrome
- Lateral epicondylitis (lateral epicondylopathy of the elbow/tennis elbow/mouse elbow/mouse arm), medial epicondylitis (golfer's elbow)
- Patella tip syndrome (jumper's knee, patellar tendinopathy)
- Achilles tendinopathy
- Plantar fasciopathy and plantar fasciitis
- Pseudoarthrosis and bone non-union, delayed union and its causes, osteochondritis dissecans and its causes, avascular necrosis (femoral head necrosis, knee)
- Medial tibial stress syndrome
- Greater trochanteric pain syndrome
- Stress fractures



Treatment recommendations



Treatment protocols/recommendations

Treatment recommendations

The following recommendations are given solely as guidelines. Although the number of pulses, frequency, energy level and distance holder values are based on clinical studies and international guidelines, they should be adjusted to the specific circumstances of the individual patient.
Treatment applied directly to bones or bony protuberances should obviously be adjusted to suit individual tolerance.
Always start the treatment with a low energy level and gradually increase, until a clearly perceptible shockwave sensation is achieved.
Ensure that the patient can give clear feedback at all times, both visually and verbally.
Although the treatment may be uncomfortable under certain circumstances, a strong sensation of pain should be avoided.

Shoulder

Area	Indication	Number of Shocks	Engery level in mj/mm	Frequency in Hz	Distance holder in mm
Shoulder	Subacromial pain syn-drome	1000	0,12	5	20
Total number of treatments	Up to five		Interval	Once or twice a week	
Shoulder	Calcifying tendinopathy of the shoulder	1500	0,15	5	20
Total number of treatments	Up to five		Interval	Once or twice a week	
Shoulder	Rotator cuff disease with/without calcification	2000	0,05	5	20
Total number of treatments	Up to five		Interval	Once or twice a week	
Shoulder	Musculoskeletal trigger point	2000	0,05	4	10
Total nr of treatments	Up to eight		Interval	Once or twice a week	

Neck

Area	Indication	Number of Shocks	Engery level in mj/mm	Frequency in Hz	Distance holder in mm
Neck	Musculoskeletal trigger point	2000	0,05	4	10
Total number of treatments	Up to eight		Interval	Once or twice a week	

Arm

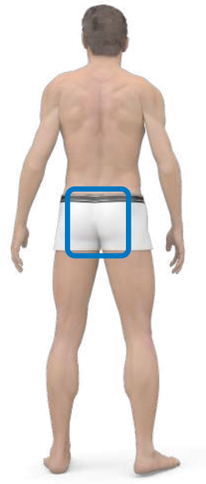
Area	Indication	Number of Shocks	Engery level in mj/mm	Frequency in Hz	Distance holder in mm
Arm	Lateral epicondylopathy of the elbow	1500	0,14	4	15
Total number of treatments	Up to three		Interval	Once or twice a week	
Arm	Medial epicondylopathy of the elbow	1500	0,14	4	15
Total number of treatments	Up to three		Interval	Once or twice a week	
Arm	Musculoskeletal trigger point	2000	0,05	4	10
Total number of treatments	Up to eight		Interval	Once or twice a week	

Hand

Area	Indication	Number of Shocks	Engery level in mj/mm	Frequency in Hz	Distance holder in mm
Hand	Musculoskeletal trigger point	2000	0,05	4	10
Total number of treatments	Up to eight		Interval	Once or twice a week	

Treatment protocols/recommendations

Hip



Area	Indication	Number of Shocks	Engery level in mj/mm	Frequency in Hz	Distance holder in mm
Hip	Greater trochanter pain syndrome	1500	0,15	4	40
Total number of treatments	Up to five		Interval	Once or twice a week	
Hip	Pseudoarthrosis	2500	0,3	3	30
Total number of treatments	Up to five		Interval	Once a week	
Hip	Musculoskeletal trigger point	2000	0,05	4	10
Total number of treatments	Up to eight		Interval	Once or twice a week	

Knee

Area	Indication	Number of Shocks	Engery level in mj/mm	Frequency in Hz	Distance holder in mm
Knee	Pseudoarthrose	2500	0,25	3	30
Total number of treatments	Up to four		Interval	Once or twice a week	
Knee	Patellar tendinopathy	1500	0,10	5	10
Total number of treatments	Three, max 5 treatments		Interval	Once a week	
Knee	Osteochondritis dissecans	2500	0,35	5	25
Total number of treatments	Up to five		Interval	Once every 1 or 2 weeks	
Knee	Musculoskeletal trigger point	2000	0,05	4	10
Total number of treatments	Up to eight			Once or twice a week	

Treatment protocols/recommendations

Leg

Area	Indication	Number of Shocks	Engery level in mj/mm	Frequency in Hz	Distance holder in mm
Leg	Tibial stress syndrome	1500	0,10	5	15
Total number of treatments	Three, max up to five treatments		Interval	Once or week	
Leg	Bone non union	2000	0,09	4	20
Total number of treatments	Up to five		Interval	Once every one or two weeks	
Leg	Delayed union	3000	0,04	3	20
Total number of treatments	Up to 4 treatments		Interval	Once or twice a week	
Leg	Stress fracture	4000	0,4	4	20
Total number of treatments	Up to 4 treatments		Interval	Once or twice a week	

Foot

Area	Indication	Number of Shocks	Engery level in mj/mm	Frequency in Hz	Distance holder in mm
Foot	Achilles tendinopathy	2000	0,10	5	10
Total number of treatments	Up to five treatments		Interval	Once a week	
Foot	Plantar Fasciitis with or without heel spur	1500	0,09	5	20
Total number of treatments	Up to five treatments		Interval	Once a week	

Gelpads

The consistency of the gel in the gelpads changes due to heat, cold, direct sunlight, mechanical damage or natural aging. Therefore, protect the gel pads from natural environmental influences.

Do not use visibly damaged gelpads.

The enShock comes with 8 gelpads to ensure optimal penetration depth. The diameter of the gelpads reflects the penetration depth. For instance, a gelpad with a diameter of 20mm leads to a maximum energy level at a depth of 20mm.The diameter of the gelpad can be read on the gelpad in question.

For more details please refer to chapter 2; Application Information, chapter 5 System set-up and chapter 7 Operation instructions in the Instructions for Use.

Foot switch

The enShock can be provided with an optional foot switch.
The foot switch has 3 buttons. The white button (left side) is used to apply the start a treatment. The middle button adjusts the energy downwards (blue). The yellow button (right side) is used to adjust the applied energy upwards.
For more information or ordering the Foot switch please contact your local distributor or sales representative.

Conducting gel

Optimal energy transfer can only be guaranteed when conductive gel is used.
Make sure to use sufficient conductive gel between handpiece and gelpad and between gelpad and skin.
For more information or ordering additional bottles with conducting gel please contact your local distributor or sales representative.

Gelpads

Foot switch

Conducting gel

Note:
Only accessories provided by Zimmer MedizinSysteme GmbH that are intended for this device may be used.

FAQ / Questions - Answers

Why choose for focused shockwave?

Focused shockwave therapy is one of the most effective, non-invasive and non-pharmaceutical treatments for several (musculoskeletal) disorders. It gives a quick response and fast results. The treatment on itself only takes 15 minutes maximum.

Are focused shockwaves painful?

Focused shockwave treatments can be uncomfortable, but thanks to precise energy settings, this can be reduced to a minimum. A possible uncomfortable feeling will stop direct after the treatment. If the patient feels some pain after a treatment, general pain medication as Paracetamol can be taken. Avoid always the use of NSAID (non-steroidal anti-inflammatory drug) as this might counteract the focused shockwave effects. For the same reason it's not recommended to use ice or cold-air direct after a treatment.
Note: Before taking any pain medication read the information leaflet, including the contraindications, carefully.

Can I use the enShock on a pacemaker?

There are no side effects reported in the literature, on the enShock it is not a contraindication. Zimmer MedizinSysteme GmbH still recommends NOT exposing a pacemaker to shockwaves.

Can I use the enShock on implants and osteosynthesis material?

There are no side effects reported in the literature. Nevertheless we recommend not directly use the enShock on implants or osteosyntesis material

How do I clean the handpiece and gelpads?

Device, handpiece and gelpads need regular cleaning and disinfection. For exact guidelines please refer to chapter 9: reprocessing, cleaning, disinfection in the Instructions for Use.

Precautions and contraindications

Caution is indicated in the case of persons:

- With sensory disturbances
- With strong autonomic dysfunction
- With osteoporosis
- Who are under the influence of drugs and/or alcohol

The device may not be used on injured skin or mucous membranes.

Contraindications

- Local infections
- Local tumour diseases
- Coagulopathy (analysis of coagulation status is necessary before use)
- Use of anti-coagulation medications
- Pregnancy
- Lung tissue or other hollow or air-filled organs in the treatment area
- Children with open epiphyses
- Epiphyseal plate in the treatment area
- Treatment area in the region of the brain or spine
- Treatment area in the region of the eyes/face

Common side effects include:

- (transient) increased pain, radiating pain
- skin irritation, skin reddening, local skin damage such as skin erythema, petechial skin bleeding, hematoma, local swelling, transient numbness
- nausea
- headache/migraine
- nerve irritation, nerve injury

References

References/Publications

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Image source references:

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Note:

Please also always follow the instructions for use for the en*Shock* device. The device may only be operated or used by skilled and specially trained operators.

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ESWT – Extra corporeal shockwave therapy focused

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