

orthoPACE™

Regenerative Medicine for Musculoskeletal Conditions



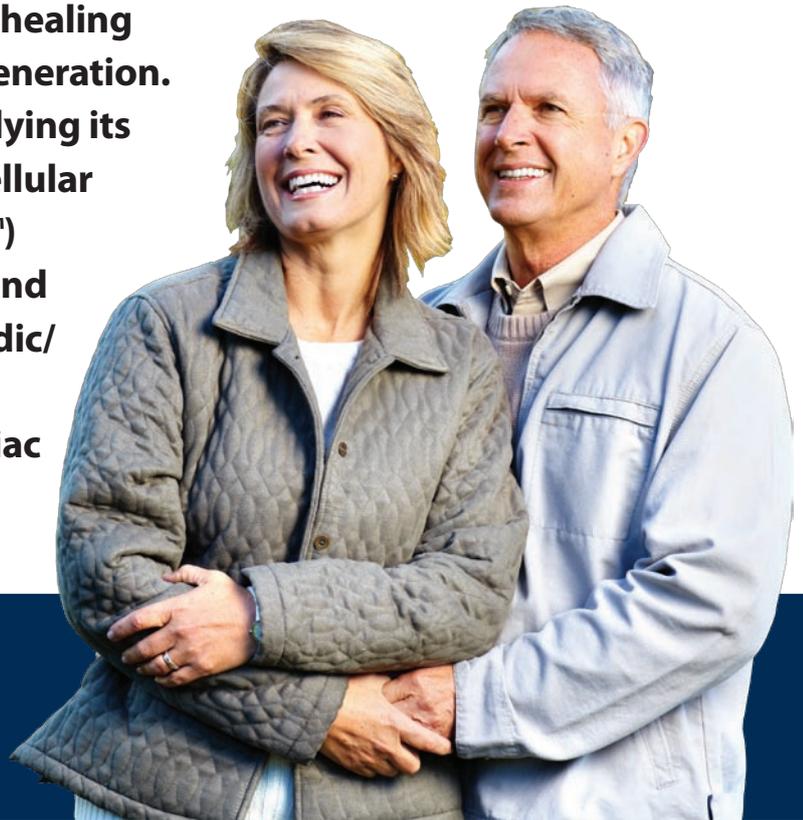
**Biological Signaling to Heal
Chronic and Acute Conditions**

SANUWAVE®
Healing today. Curing tomorrow.

SANUWAVE®



SANUWAVE, Inc. is an emerging leader in the development and commercialization of noninvasive, biological response activating devices in the regenerative medicine area for the repair and regeneration of tissue, musculoskeletal and vascular structures. SANUWAVE's portfolio of products and product candidates activate biological signaling and angiogenic responses, including revascularization and microcirculatory improvement, helping restore the body's normal healing processes and regeneration. SANUWAVE is applying its Pulsed Acoustic Cellular Expression (PACE™) technology in wound healing, orthopaedic/spine, plastic/cosmetic and cardiac conditions.



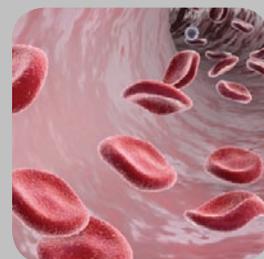
Headquartered in Alpharetta, GA, SANUWAVE designs, manufactures, markets, and services its industry leading products worldwide.

Pulsed Acoustic Cellular Expression

The orthoPACE™ is a device in the PACE™ Technology platform designed for specialists in orthopaedics, trauma and sports medicine. This award winning* device generates electrohydraulic shock waves that have a biological activating effect that regenerates hard and soft musculoskeletal tissues such as bone, tendons and ligaments.

How does PACE™ Technology Work?

Pulsed Acoustic Cellular Expression (PACE™) technology is well suited for an array of applications due to its stimulation of a broad spectrum of cellular events critical for the initiation and progression of healing of many common conditions, such as tendinopathy, bursitis and fracture.



- Doppler images have demonstrated immediate increased perfusion as a result of PACE™ treatment.¹
- PACE™ biological signaling increases leukocyte (white blood cell) activity resulting in enhanced microcirculation.²
- Cellular Expression of cytokines and growth factors (such as BMP, VEGF, PCNA and eNOS) stimulate endothelial cell growth and fibroblast proliferation.^{2,3}
- PACE™ induces neovascularization, allowing improved blood gases and nutrients to enter the treatment area.

* Design won the 2001 Good Design Award presented by the Chicago Athenaeum.

Indications

Trauma

Pseudarthrosis

A published retrospective study reported complete bony union in tibial nonunion fractures at a mean time of 4.8 +/- 4.0 months.⁴



Sports Medicine

Patellar Tip Syndrome (Jumper's Knee)

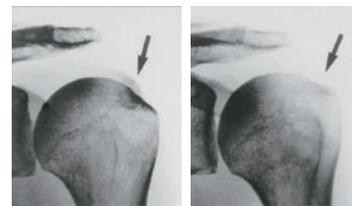
At 2-3 year follow-up, 90% of patients reported excellent to good results in a randomized, controlled study.⁵



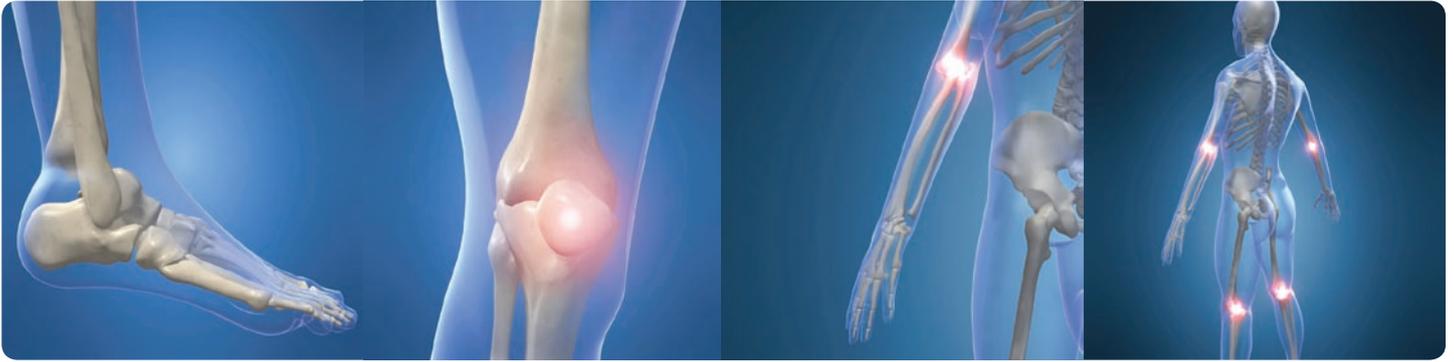
Sports Medicine

Tendinosis Calcarea

A prospective, controlled study reported improvement in 91% of patients after 2-3 years.⁶



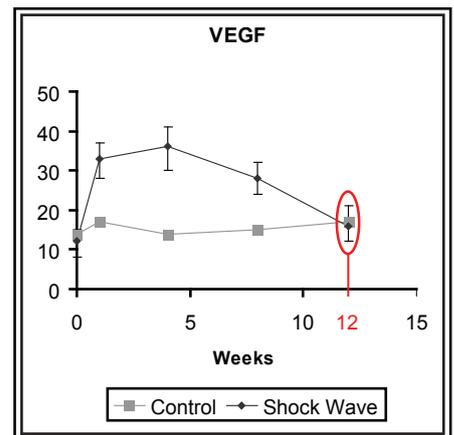
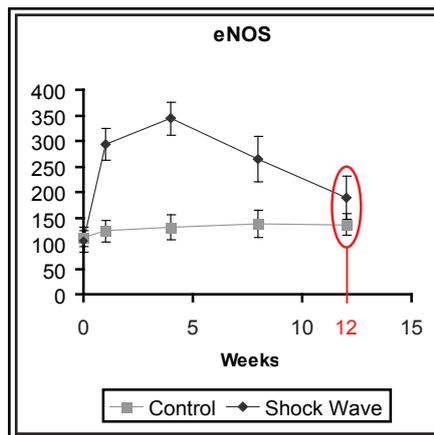
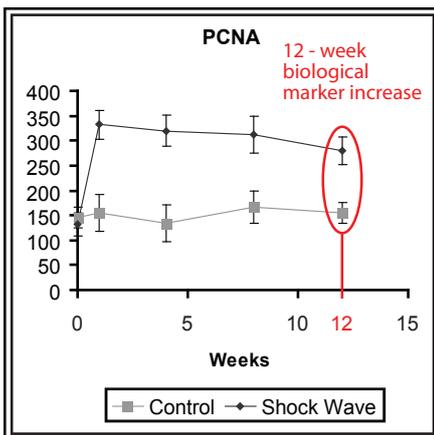
on (PACE™) Treatment in Orthopaedics



Biological Signaling Evidence

Dr. Ching-Jen Wang, MD of Chang Gung University in Taiwan

Increases in cellular signaling were apparent during Dr. Wang's mechanism of action research study. Biological markers that would indicate healing, including eNOS (benefits oxygenation), VEGF (increases blood flow) and PCNA (increases cellular proliferation), increased after treatment. The effects lasted up to 12 weeks before declining to normal levels. In comparison, the control samples did not demonstrate any positive cellular changes during the study.³



The working mechanisms described above stimulate biological effects including tissue regeneration.

Sports Medicine

Plantar Fasciitis (Painful Heel Syndrome)

A prospective, randomized, controlled, blinded study reported 77% of patients had excellent to good outcomes.⁷



Sports Medicine

Achillodynia

83% of patients with chronic noninsertional Achilles tendinopathy had excellent to good outcomes after 12 months as reported in a prospective, controlled study.⁸



Sports Medicine

Epicondylitis

Positive outcomes were reported after 8 weeks for 90% of patients participating in a prospective, randomized, controlled, blinded study.⁹



orthoPACE™

1 Leading Edge Technology

- orthoPACE™ generates powerful electrohydraulic shock waves via spark gap technology characterized by an ultra-short rise time and high peak pressure
- A large focal area ensures consistent distribution of energy to the entire treatment area
- Multiple treatment applicators are available for different penetration depths
- New, superficial applicator can be less painful for soft tissue, tendon, joint and small extremity bones
- Sterile sleeve barriers and sterile gel now available

2 User Friendly

- The ergonomic treatment applicator of the orthoPACE™, the orthoPACE™ Applicator, is attached to a flexible cable for easy positioning
- Plug-and-play technology and intuitive user interfaces enable an efficient treatment
- The compact design is particularly suitable for the small practice setting or wherever limited space is an issue

3 Cost Effective

- Only 1 or 2 treatments are required to treat a patient successfully
- Amortization time is short with just a few patients per month
- The treatment takes only minutes to complete
- Value creation is possible by offering patients the most advanced technology

4 Broad Range of Applications

- orthoPACE™ can be used for any of the indications described in this brochure
- orthoPACE™ can be used as an adjunctive treatment to accelerate healing and improve clinical outcomes and healthcare economics
- orthoPACE™ can also be used to treat any painful bone near soft tissue diseases

Orthopaedics

Osteoarthritis

The majority of treated patients reported improvement in pain, and functional tests showed improved movement, and reduced swelling and joint stiffness. Osteochondral repopulation has been reported in studies.



Orthopaedics / Trauma

Adjunctive Use of orthoPACE™

Conditions that require fixation, fusion and grafts have reported a lower rate of nonunion, accelerated healing, and an increased bone mass and density after treatment with PACE™. Studies are also ongoing to determine if treatment with PACE™ could lead to decreased rates of infection and decreased incidences of orthopaedic implant loosening.



Technical Data

Power supply
100 - 240 V, 50/60 Hz

Dimensions
Height: 21.9 cm
Width: 47.3 cm
Length: 42.6 cm
Weight: 16 kg

Performance range
6 different energy levels

Pulse rate
60, 120, 180, 240 pulses/minute

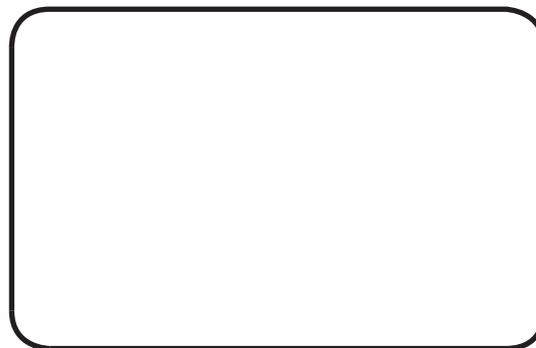
Configuration
mobile, portable unit

Certification
Medical Device Directive 93/42/EEC
MDD Annex II, Class IIb
Standards (Extract of complete list)
IEC 60601-1

Consumables & Accessories:
orthoPACE™ Applicators
Lifetime of 75,000 pulses
Optional Sterile Sleeve
Optional Sterile Gel

Options:
Carrying Case

Distributor:



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3. Wang et al. Shock Wave Therapy Induces Neovascularization at the Tendon-Bone Junction. *Journal of Orthopaedic Research*, 21:984-989, 2003.
4. Elster et al. Extracorporeal Shock Wave Therapy for Nonunion of the Tibia. *J Orthop Trauma*, Vol 24, No. 3, March 2010.
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8. Alvarez et al. Lateral Epicondylitis Study filed with FDA, on file with SANUWAVE. 2003.
9. Ogden et al. Electrohydraulic High-Energy Shock-Wave Treatment for Chronic Plantar Fasciitis. *J Bone Joint Surg Am*, 86:2216-2228, 2004.

**New
Superficial,
Reduced Pain
Applicator**



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The technical data corresponds to the state of technology at the time of publication. SANUWAVE reserves the right to make changes or modifications.