NEW GENERATION OF SHOCKWAVE DEVICES WITH THE CONTROLS IN THE HANDPIECE

Shockwave CANADA INC.

Non Surgical Treatment of Soft Tissue, Bone, Heel and Joint Pain

CONTENTS

THE ULTIMATE SHOCKWAVE DEVICE

The Tissue Regenerator is the world's most effective Shockwave treatment and can be used affordably by all Health Care practitioners.

Business/Revenue Opportunity

The Shockwave Tissue Regenerator offers the ultimate opportunity for business building and boosting your bottom line. With success measured by clearly defined goals and calculated return on investment, affordable treatment is available through attractive lease or purchase terms. Anyone can be trained to operate the Tissue Regenerator, which is proven to be the 'standard of care' and treatment of choice for many conditions.

CONDITIONS THAT CAN BE TREATED BY SHOCKWAVE THERAPY

- Plantar Fasciitis/Heel Spur
- Achilles Tendinopathy
- Myofascial Trigger Points
- Jumper's Knee
- Stress Fractures
- Bursitis
- Hallux Rigidus
- Shin Splints
- Tennis Elbow
- Non-Healing Ulcers
- Calcific Rotator Cuff Tendonitis
- Scar Tissue Treatment
- Hamstring Tendinopathy
- Osgood-Schlater
- Muscle and connective tissue activation with V-ACTOR.

BENEFITS

- Non-surgical treatment
- No side effects
- Accelerates healing
- Can be used by all health practitioners
- Affordable
- Coverage available from most insurance companies

Success Rates

91% improvement for Calcific Tendonitis
– Journal of American Medical Association, 2003

90% success rate for Plantar Fasciitis
– Foot & Ankle International, 2012

77% improvement for Tennis Elbow
– The Journal of Orthopaedics, 2005

76% success rate for Achilles Tendinopathy
– The American Journal of Sports Medicine, 2007

8 times more effective for Hamstring Tendinopathy than regular physiotherapy and chiropractic treatment
— The American Journal of Sports Medicine, 2010

A non-invasive surgical solution that accelerates the recovery from injured tissue.

THE SUPERIOR TECHNOLOGY OF STORZ

When you compare Storz and Shockwave Canada to other systems on the market, you'll find that Storz is simply the most advanced, least expensive and has the most reliable technology available. Storz is also the category leader in research and development. Shockwave Canada provides unequalled medical support behind your lease or purchase. Here's the proof:

1. World's most effective Shockwave treatment
   - 'Radial extracorporeal Shockwave therapy significantly improves pain, function, and quality of life' - The American Journal of Sports Medicine, 2008
   - 'Shockwave therapy can effectively decrease plantar fascia thickness as demonstrated objectively by ultrasound evaluation and significantly reduces patient-reported pain' - Foot & Ankle International, 2012
2. Newly developed hand control, with all main operating elements integrated into the handpiece. This allows for safer treatments on patients as changes can be made to settings without looking away from the patient
   - Frequency, energy levels and number of shocks applied can be adjusted directly via selector buttons. Only product of its kind on the market
3. State of the art titanium and ceramic heads for superior comfort, manufactured for exclusive distribution by Shockwave Canada
4. Proven research and development with our products
5. Renowned medical advisors available at no charge
6. Published and proven treatment protocols with our technology
7. World class institutions using our technology
   - Cleveland Clinic
   - Johns Hopkins University
   - Mount Sinai Hospital
   - Montreal General Hospital
   - Duke University
   - University of Toronto
   - McGill University
   - Queen's University
   - Canadian Memorial Chiropractic College
8. No replacement of applicator heads necessary
9. Storz has over 60 years of experience
10. Vibration-Shock technology treats acute and chronic injuries
11. Storz is a world leader in:
    - Effectiveness
    - Medical support
    - Research and development
    - Technology

Shockwave is the Treatment of Choice

Visit our website for more information on products and scientific evidence:
www.shockwavecanadainc.ca

PRODUCTS

MASTERPULS® Superiority

In the field of pain therapy and rehabilitation, MASTERPULS® Shockwave systems are a must-have for any modern, successful medical practice. Manufactured in Switzerland, the MP 50, 100 and 200 are superior quality devices offering ease of use and simple handpiece servicing at reduced costs. Compared to other Shockwave systems, MASTERPULS® products are simply the most advanced technology available.

MASTERPULS® MP50

The Compact Radial Shockwave System
The elimination of pain symptoms ensures rapid improvement in mobility and increased strength in the treated regions. Up to 91% of patients respond well or very well to MASTERPULS® Shockwave therapy

KEY FEATURES AT A GLANCE

The highlights of this exceptionally efficient Shockwave system are:

- Compact design
- Low capital expenditure and maintenance costs
- Maximum mobility, can be easily carried anywhere
- Newly developed hand control, with all main operating elements integrated into the handpiece. Frequency, energy levels and number of shocks applied can be adjusted directly via selector buttons. Only product of its kind on the market. This allows for safer treatments on patients as changes can be made to settings without looking away from the patient
- Vibration therapy (V-ACTOR.)

Facts and Figures

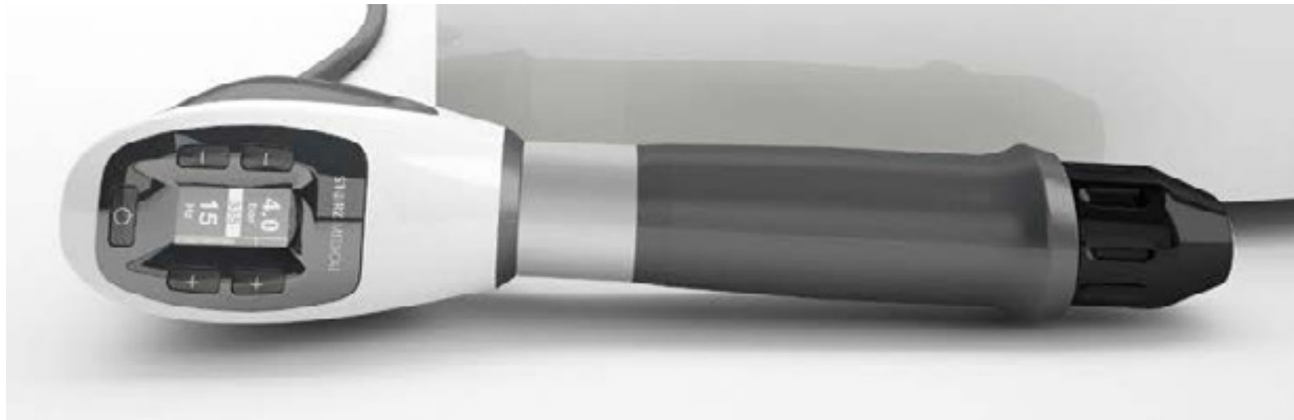
- Compact and mobile: 9.5 kg
- Built-in compressor
- Control and display all on handpiece
- Hand operated Shockwave devices

Parameters

- Shock frequency: 1 – 15 Hz
- Application pressure: 1 – 4 bar/11 MPa

Indications

- Treatment of Tendinopathies
- Trigger point therapy
- Activation and loosening of muscle and connective tissue
- Acupuncture Shockwave therapy



The New MASTERPULS® MP100

The 'Ultra' System in Radial Shockwave Therapy
The new MASTERPULS® MP100 creates a perfect balance between performance and efficiency, mobility and weight, versatility and low maintenance costs.

KEY FEATURES AT A GLANCE

- Newly developed hand control, with all main operating elements integrated into the handpiece. Frequency, energy levels and number of shocks applied can be adjusted directly via selector buttons. Only product of its kind on the market. This allows for safer treatments on patients as changes can be made to settings without looking away from the patient
- Compact design
- Built-in high-performance compressor makes the system even more powerful and provides excellent therapy success rates
- Low maintenance costs
- Combinable handpieces
- Radial Shockwave therapy with various shock transmitters
- Vibration therapy (V-ACTOR®)

Pulse Frequency/Pressure
- Radial Shockwave therapy: 1 – 21 Hz/1 – 5 bar
- Vibration therapy (V-ACTOR®): 31 Hz

Oscillating 'D-ACTOR®' Technology
- For better myofascial Trigger Point therapy

'Deep Impact' Shock Transmitter
- For the treatment of deep pain regions

'CERAma-x™' Shock Transmitter
- Elastic shock transmitter for Shockwave

'V-ACTOR®' handpiece
- For muscle and connective tissue activation/smoothing

Indications
- Treatment of Tendinopathies
- Hamstrings
- Myofascial trigger points
  1. Achilles Tendinopathy
  2. Bursitis
  3. Hallux Rigidus
  4. Non-Healing Ulcers
  5. Tendonitis
  6. Scar Tissue
- Shoulder pain
- Shin Splints
- Tennis Elbow
- Patellar Tendonitis
- Plantar Fasciitis/Heel Spur
- Shin Splints
- Stress Fractures
- Enhancement of bone healing
- Muscle and connective tissue activation with V-ACTOR®
- Osgood-Schlatter

Indications Success Rate

Calcific Rotator Cuff Tendonitis	91%
Plantar Fasciitis	90%
Achilles Tendinopathy	76%
Hamstring Tendinopathy	80%
Tennis Elbow	77%
Myofascial trigger points	80%
Acupuncture Shockwave Therapy	up to 90%

Facts and Figures
- Hand operated Shockwave devices
- Built-in high-performance 'Silent' compressor
- Extended frequency/power range: 21 Hz/5.0 bar
- Precision pressure controller
- V-ACTOR® vibration therapy: 31 Hz
- System weight: 10.5 kg

SCIENTIFIC EVIDENCE

Study #1 - Radial Extracorporeal Shockwave Therapy is Safe and Effective in the Treatment of Chronic Recalcitrant Plantar Fasciitis. Results of a Confirmatory Randomized Placebo-Controlled Multi-center Study.

Ludger Gerdesmeyer, MD, PhD, Carol Frey, MD, Johannes Vester, PhD, Markus Maier, PhD, Lowell Weil Jr, DPM, Lowell Weil Sr, DPM, Martin Russlies, PhD, John Stienstra, DPM, Barry Scurran, DPM, Keith Fedder, MD, Peter Diehl, MD, Heinz Lohrer, MD, Mark Henne, MD, and Hans Gollwitzer, MD. From the Department of Orthopaedic and Trauma, Technical University Munich, Klinikum Rechts der Isar, Germany, the Department of Joint Arthroplasty and Clinical Science, Mare Clinic, Kiel, Germany, Orthopaedic Foot and Ankle Center, Manhattan Beach, California, IDV Data Analyses and Study Planning, Biometrics in Medicine, Gauting, Germany, the Department of Orthopaedics, Ludwig Maximilian University, Munich, Germany, the Weil Foot and Ankle Institute, Des Plaines, Illinois, University Schleswig Holstein, Campus Lübeck, Lübeck, Germany, the Department of Podiatry, The Permanente Medical Group Inc, Union City, California, the Department of Orthopaedics, University Rostock, Rostock, Germany, and the Institute of Sports Medicine, Frankfurt Main, Germany.

Background:

Radial extracorporeal Shockwave therapy is an effective treatment for chronic plantar fasciitis that can be administered to outpatients without anesthesia but has not yet been evaluated in controlled trials.

Hypothesis:

There is no difference in effectiveness between radial extracorporeal Shockwave therapy and placebo in the treatment of chronic plantar fasciitis.

Study Design:

Randomized, controlled trial; level of evidence, 1.

Methods:

Three interventions of radial extracorporeal Shockwave therapy (0.16 mJ/mm 2; 2000 impulses) compared with placebo were studied in 245 patients with chronic plantar fasciitis. Primary endpoints were changes in visual analog scale composite score from baseline to 12 week follow-up, overall success rates and success rates of the single visual analog scale scores (heel pain at first steps in the morning, during daily activities, during standardized pressure force). Secondary endpoints were single changes in visual analog scale scores, success rates, Roles and Maudsley score, SF-36, and patients' and investigators' global judgment of effectiveness 12 weeks and 12 months after extracorporeal Shockwave therapy.

Results:

Radial extracorporeal Shockwave therapy proved significantly superior to placebo with a reduction of the visual analog scale composite score of 72.1% compared with 44.7% (P = .0220), and an overall success rate of 61.0% compared with 42.2% in the placebo group (P = .0020) at 12 weeks. Superiority was even more pronounced at 12 months, and all secondary outcome measures supported radial extracorporeal Shockwave therapy to be significantly superior to placebo (P < .025, 1-sided). No relevant side effects were observed.

Conclusion:

Radial extracorporeal Shockwave therapy significantly improves pain, function and quality of life compared with placebo in patients with recalcitrant plantar fasciitis.

Source:

American Journal of Sports Medicine, 2008; 36: 2100-2109. DOI: 10.1177/0363546508324176

For more information visit:
shockwavecanadainc.ca/scientific-evidence.

Study #2 - Ultrasonographic Evaluation of Low Energy Extracorporeal Pulse-Activated Therapy (EPAT) for Chronic Plantar Fasciitis

By Robert Gordon, MD; Charles Wong, BHSc; Eric J. Crawford, BHSc Toronto, Canada

Background:

Ultrasonographic measurement of the plantar fascia can be used to objectively diagnose plantar fasciitis. The purpose of this study was to determine the long-term effectiveness of Extracorporeal Pulse-Activated Therapy (EPAT) - Shockwave therapy - for the treatment of plantar fasciitis using ultrasonographic measurement as an objective outcome measure, with a minimum follow-up of 12 months.

Methods:

Patients with chronic recalcitrant plantar fasciitis were prospectively recruited and underwent EPAT. Ultrasound measurement of the plantar fascia and patient-rated pain scores were collected before treatment and at follow-up (minimum of 12 months post-treatment). Twenty-five subjects (35 feet) met the inclusion criteria. The average follow-up time was 29.4 ± 13.1 (M ± SD; range, 12 to 54) months.

Results:

The average thickness of the plantar fascia of the symptomatic heels was 7.3 ± 2.0 mm before treatment and 6.0 ± 1.3 mm after treatment ($p < 0.001$). The average change in thickness of the treated heels was – 1.3 mm (– 0.8 to – 1.8 mm; 95% CI, $p < 0.0001$). No correlation was found between length of follow-up and change in ultrasound measured plantar fascia thickness ($r = – 0.04$, $p = 0.818$).

Conclusion:

For patients with a greater than 12-month history of heel pain, Shockwave therapy can effectively decrease plantar fascia thickness as demonstrated objectively by ultrasound evaluation and reduce patient-reported pain. No relationship between length of follow-up and change in plantar fascia thickness was found after 12 months.

Source:

FOOT & ANKLE INTERNATIONAL ©2012 by the American Orthopaedic Foot & Ankle Society DOI: 10.3113/FAI.2012.0202

For more information visit:
shockwavecanadainc.ca/scientific-evidence

Study #3 - Shockwave Therapy for the Treatment of Chronic Proximal Hamstring Tendinopathy in Professional Athletes

By Angelo Cacchio, MD, Jan D. Rompe, MD, John P. Furia, MD, Piero Susi, MD, Valter Santilli, MD, and Fosco De Paulis, MD
Investigation performed at Sciuba Diagnostic Imaging and Rehabilitation Center, Sulmona, Italy

Background:
Chronic Proximal Hamstring Tendinopathy is an overuse syndrome that is usually managed by non-operative methods. Shockwave therapy has proved to be effective in many tendinopathies.

Hypothesis:

Shockwave therapy may be more effective than other non-operative treatments for Chronic Proximal Hamstring Tendinopathy.

Study Design:

Randomized controlled clinical study; level of evidence, 1.

Methods:

Forty professional athletes with Chronic Proximal Hamstring Tendinopathy were enrolled between February 1, 2004 and September 30, 2006. Patients were randomly assigned to receive either Shockwave therapy, consisting of 2500 impulses per session at a 0.18 mJ/mm energy flux density without anesthesia, for 4 weeks (SWT group, n = 20), or traditional conservative treatment consisting of non-steroidal anti-inflammatory drugs, physiotherapy and an exercise program for hamstring muscles (TCT group, n = 20). Patients were evaluated before treatment, 1 week and 3, 6, and 12 months after the end of treatment. The visual analog scale (VAS) score for pain and Nirschl phase rating scale (NPRS) were used as primary outcome measures.

Results:

The patients were observed for a mean of 10.7 months (range, 1-12 months). Six patients were lost to follow-up because they underwent a surgical intervention: 3 (all in TCT group) were lost at 3 months; 2 (1 in each group), at 6 months; and 1 (in the TCT group), at 12 months. Primary follow-up was at 3 months after the beginning of treatment. The VAS scores in the SWT and TCT groups were 7 points before treatment ($P = .84$), and 2 points and 5 points, respectively, 3 months after treatment ($P < .001$). The NPRS scores in the SWT and TCT groups were 5 points in either group before treatment ($P = .48$), and 2 points and 6 points, respectively, 3 months after treatment ($P < .001$). At 3 months after treatment, 17 of the 20 patients (85%) in the SWT group and 2 of the 20 patients (10%) in the TCT group achieved a reduction of at least 50% in pain ($P < .001$). There were no serious complications in the SWT group.

Conclusion:

Shockwave therapy is a safe and effective treatment for patients with Chronic Proximal Hamstring Tendinopathy.

Source:
American Journal of Sports Medicine, 2011; 39: 146
DOI: 10.1177/0363546510379324

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Study #4 - Low-Energy Extracorporeal Shockwave Therapy as a Treatment for Medial Tibial Stress Syndrome

By Jan D. Rompe, MD, Angelo Cacchio, MD, John P. Furia, MD, and Nicola Maffulli, MD, MS, PhD, FRCS(Orth), FFSEM(UK)
From OrthoTrauma Evaluation Center, Mainz, Germany, the Department of Medicine and Physical Rehabilitation, San Salvatore Hospital of L'Aquila, Italy, SUN Orthopaedics, Lewisburg, Pennsylvania, and the Centre for Sports and Exercise Medicine, Barts, and The London School of Medicine and Dentistry, London, England

Background:

Medial tibial stress syndrome (MTSS) is a pain syndrome along the tibial origin of the tibialis posterior or soleus muscle. Extracorporeal Shockwave therapy (SWT) is effective in numerous types of insertional pain syndromes.

Hypothesis:

Shockwave therapy is an effective treatment for chronic MTSS.

Study Design:

Cohort study; level of evidence, 3.

Methods:

Forty-seven consecutive subjects with chronic recalcitrant MTSS underwent a standardized home training program, and received repetitive low-energy radial SWT (2000 shocks; 2.5 bars of pressure, which is equal to 0.1 mJ/mm 2; total energy flux density, 200 mJ/mm2; no local anesthesia) (treatment group). Forty-seven subjects with chronic recalcitrant MTSS were not treated with SWT, but underwent a standardized home training program only (control group). Evaluation was by change in numeric rating scale. Degree of recovery was measured on a 6-point Likert scale (subjects with a rating of completely recovered or much improved were rated as treatment success).

Results:

One month, 4 months and 15 months from baseline, success rates for the control and treatment groups according to the Likert scale were 13% and 30% ($P < .001$), 30% and 64% ($P < .001$), and 37% and 76% ($P < .001$), respectively. One month, 4 months and 15 months from baseline, the mean numeric rating scale for the control and treatment groups were 7.3 and 5.8 ($P < .001$), 6.9 and 3.8 ($P < .001$), and 5.3 and 2.7 ($P < .001$), respectively. At 15 months from baseline, 40 of the 47 subjects in the treatment group had been able to return to their preferred sport at their pre-injury level, as had 22 of the 47 control subjects.

Conclusion:

Shockwave therapy as applied was an effective treatment for MTSS.

Source:

American Journal of Sports Medicine 2010, 38: 125
originally published online September 23, 2009
DOI: 10.1177/0363546509343804

For more information visit:
shockwavecanadainc.ca/scientific-evidence

Study #5 - Eccentric Loading, Shockwave Treatment, or a Wait-and-See Policy for Tendinopathy of the Main Body of Tendo Achillis - A Randomized Controlled Trial

Jan D. Rompe, MD, Bernhard Nafe, MD, John P. Furia, MD, PhD, and Nicola Maffulli, MD, PhD, FRCS(Orth)
From the OrthoTrauma Clinic, Gruenstadt, Germany, Rüsselheim-Bauschheim, Germany, the SUN Orthopaedic Group, Lewisburg, Pennsylvania, and the Department of Trauma and Orthopaedic Surgery, Keele, University of Medicine, Staffordshire, England

Background:

Few randomized controlled trials compare different methods of management in chronic tendinopathy of the main body of Tendo Achillis.

Purpose:

To compare the effectiveness of 3 management strategies – group 1, eccentric loading; group 2, repetitive low-energy Shockwave therapy (SWT); and group 3, wait and see – in patients with chronic tendinopathy of the main body of Tendo Achillis.

Study Design:

Randomized controlled trial; level of evidence, 1.

Methods:

75 patients with a Chronic Recalcitrant (>6 months) non-insertional Achilles Tendinopathy were enrolled in a randomized controlled study. All patients had received unsuccessful management for >3 months, including at least (1) peritendinous local injections, (2) non-steroidal anti-inflammatory drugs, and (3) physiotherapy. A computerized random-number generator was used to draw up an allocation schedule. Analysis was on intention-to-treat basis.

Results:

At 4 months from baseline, the Victorian Institute of Sport Assessment (VISA)-A score increased in all groups, from 51 to 76 points in group 1 (eccentric loading), from 50 to 70 points in group 2 (repetitive low-energy SWT), and from 48 to 55 points in group 3 (wait and see). Pain rating decreased in all groups, from 7 to 4 points in group 1, from 7 to 4 points in group 2, and from 8 to 6 points in group 3. 15 of 25 patients in group 1 (60%), 13 of 25 patients in group 2 (52%), and 6 of 25 patients in group 3 (24%) reported a Likert scale of 1 or 2 points ("completely recovered" or "much improved"). For all outcome measures, groups 1 and 2 did not differ significantly. For all outcome measures, groups 1 and 2 showed significantly better results than group 3.

Conclusion:

4-month follow-up, eccentric loading and Shockwave therapy showed comparable results. The wait-and-see strategy was ineffective for the management of Chronic Recalcitrant Tendinopathy of the main body of the Achilles Tendon.

Source:

American Journal of Sports Medicine, 2007; 35: 3
DOI: 10.1177/0363546506295940

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Study #6 - Radial Shockwave Therapy in Calcifying Tendonitis of the Rotator Cuff – A Prospective Study

By P. Magosch, S. Lichtenberg, P. Habermeyer. Schulter- und Ellenbogenchirurgie, ATOS-Praxisklinik, Heidelberg, Germany

Aim:

The aim of the study was to evaluate the influence of radial Shockwave therapy (RSWT) on the course of Calcifying Tendonitis of the Rotator Cuff.

Material and Methods:

35 patients with a mean age of 47.5 years suffering for an average of 28 months from Calcifying Tendonitis with a Gaertner type 2 calcific deposit with a mean size of 16.6 mm in typical location (true a.p. view) were treated by low energy RSWT three times. The acromiohumeral distance averaged 10.4 mm measured on the true a.p. view. All patients were followed up clinically and radiologically 4 weeks, 3, 6 and 12 months after the last treatment.

Results:

The constant score improved significantly ($p < 0.0001$) during the first 4 weeks after RSWT from a mean of 68.5 to a mean of 80.5 points and remained approximately constant at 3, 6 and 12 months follow-up. After 4 weeks, 25.7% of the patients had no pain and 54.3% reported pain relief. 80.8% of the patients were painfree and 19.2% reported pain relief 12 months after RSWT. Radiologically, no calcific deposit was visible in 17.6% 4 weeks after RSWT. There was disintegration in 20.5% and no change in the calcific deposit was apparent in 61.5%. At further follow-up we found complete resorption of the calcific deposit in 75% up to 12 months after RSWT and there was no change in 25%. Overall three patients (8.5%) had to undergo surgical treatment 3-7 months after RSWT.

Conclusion:

Shockwave therapy leads to significant pain relief and an improvement in shoulder function within the first 4 weeks. In view of the long history, the size and the spontaneous resorption rate of the calcific deposit, an inductive effect of RSWT on the resorption of the calcific deposit can be assumed.

Source:

Z Orthop Ihre Grenzgeb. 2003 Nov-Dec;141(6):629-36.

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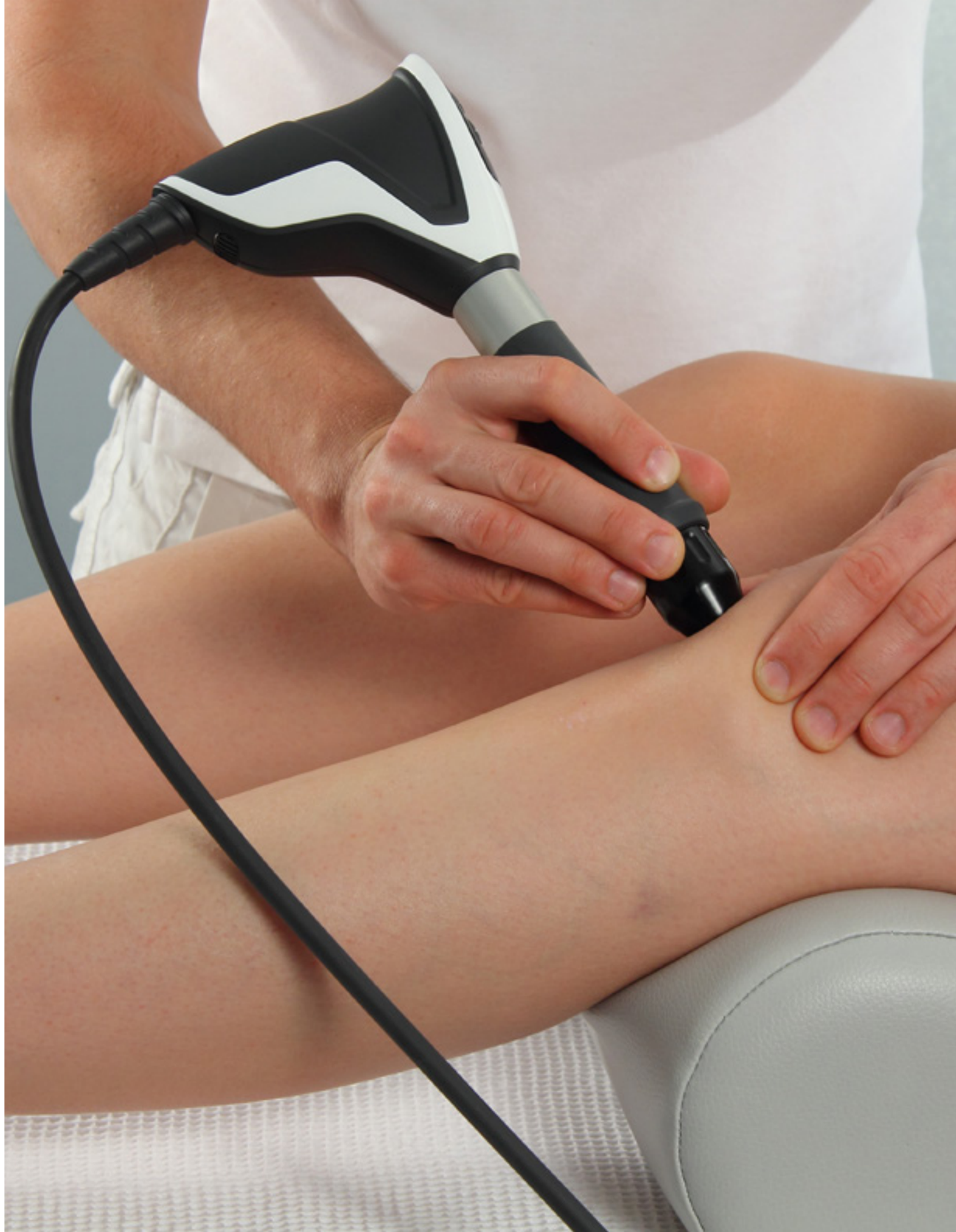

When you consider all the superior benefits, you can understand why Shockwave Canada Inc. is the only choice that makes sense.

Shockwave CANADA INC.

Non Surgical Treatment of Soft Tissue, Bone, Heel and Joint Pain

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