ORBASONE

PAIN RELIEF SYSTEM

OPERATOR MANUAL

VERSION 2.3

(August 2005)

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Caution: Federal law restricts this device to sale by or on the order of a physician.

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1. INTRODUCTION:

The Orbasone™ Pain Relief System has been designed for use by medical professionals.

The Orbasone™ Pain Relief System works to to relieve pain associated with plantar fasciitis by delivering a percussive, rather than circular energy pulse. Ordinary pain relief systems and massagers exert their force in a horizontal direction (like an electric sander).

However, the Orbasone™ Pain Relief System directs its therapeutic energy waves vertically, i.e., downward from the anatomically positioned massage sphere (i.e., reflector assembly). The result is an energy wave which penetrates below the skin, delivering relief where it is needed.

2. INDICATION FOR USE:

The Orbasone Pain Relief System is intended for extracorporeal shock wave therapy for the treatment of chronic proximal plantar fasciitis in patients 18 years of age or older that has failed to respond to conservative therapy. Chronic proximal plantar fasciitis is defined as heel pain in the area of the insertion of the plantar fascia on the medial calcaneal tuberosity that has persisted for six months or more.

3. CONTRAINDICATIONS:

Use of the Orbasone Pain Relief System is contraindicated in the following situations:

- Over or near bone growth centers until bone growth is complete.
- When a malignancy is known to be present in or near the treatment area.
- Not for use in open wounds, skin rashes, swollen, inflamed, or infected areas.
- Not for use over ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis may result.

- Patient has coagulation disorder or is taking anticoagulant medications, either for acute or chronic anticoagulant therapy.
- Patient has infection at the area to be treated. This is due to the risk of spreading infection.
- This product contains rubber latex which may cause allergic reactions.

4. WARNINGS

- The operator should avoid directing the device's focal point to main nerves or vessels to avoid injury to these structures.
- Patients currently undergoing systemic anticoagulation therapy, or other medications that might prolong bleeding time (such as aspirin) should consult with their physicians regarding temporary discontinuation of such medications before beginning treatments to prevent potential ecchymosis, bruising, or hematoma.
- The safety and effectiveness of the Orbasone Pain Relief System in patients who are pregnant, who are under 18 years of age, or who have had prior surgery for plantar fasciitis, have not been demonstrated. The Orbasone is indicated only for patients 18 years of age or older.
- Do not touch high voltage cable when system is "ON".
- Never leave the Orbasone unattended.
- Do not operate the unit if the power cord is frayed or damaged.
- Do not operate where aerosol products or oxygen are being used.

5. PRECAUTIONS

- It is recommended that there be no less than a 12 week interval between treatments. As the clinical study has shown, patients' relief of pain should continue for up to 12 weeks after a treatment session.
- The safety and effectiveness of the Orbasone Pain Relief System has not been evaluated in treatments of over 2000 pulses.
- If the patient has significant tears of the plantar fascia, shock wave treatment may be ineffective.

- If the patient has significant tears of the plantar fascia, shock wave treatment may be ineffective.

- Although no patients in the Orbasone clinical study experienced a vaso-vagal reaction during treatment, this reaction has been reported with similar equipment. If this reaction occurs, the treatment should be interrupted and the patient reclined to a supine position until symptoms disappear.

- The Orbasone Pain Relief System should be operated and used by authorized and trained personnel only. The system should be used only under the supervision of a licensed physician.

- All operator manual instructions should be followed.

- The use of ear plugs or hearing protection devices by the patient, operators and observers is recommended.

- The high voltage power supply of your system generates a high voltage pulse between 10 and 22KV. The power supply panel should never be opened, except by trained personnel. Do not remove any of the covers or panels. Electric shocks could result.

- To ensure safe operation of the system, a maintenance program should be performed a minimum of two times per year. This maintenance procedure should be performed by an engineer trained by Orthometrix personnel. Only trained engineers should be permitted to open the system and change components such as the high voltage generator and high voltage power supply.

- If there is an abnormality in the high voltage part resulting in excessively high voltage, the voltage overload prevention circuit will be activated. If an overload is generated, do not attempt to operate the unit until the cause of the trouble is clarified.

- Confirm that there is a properly connected ground wire. When there is an abnormality, address it only in the prescribed manner. In the event of electrical shock, immediately turn the power off, seek medical attention, and notify the Orthometrix representative.

- Do not spill water on the unit's electrical parts.

- Proper ventilation is required for safe operation.

- Do not overload power outlets. This can result in fire and electrical failures.

- Fuse replacements must be of identical type and value.
- Do not rest anything on top of the power cord.
- Do not walk on power cord.
- Do not modify this system.
- Use proper procedures to position the reflector.
- Lock the wheel pedal brakes before use of this device.
- Do not keep any flammable or explosive materials in the vicinity of the equipment.
- Replace electrode after each treatment.
- Remove the key when the device is not in use. [Note: The key can only be removed when in the "OFF" position.]
- Always unplug the device after use and before cleaning or servicing.
- Do not use outdoors.

Additionally, the Orbasone Pain Relief System has not been tested on persons who have the following conditions. Its safety and effectiveness are not known for someone with:

- Tarsal tunnel syndrome, or other nerve entrapment disorder (damage or pressure on the nerves to the foot).
- Diabetic neuropathy (nerve damage due to diabetes).
- Fracture of the foot or ankle.
- Significant peripheral vascular disease (circulation problems of the foot and/or leg).
- Severe osteoarthritis.
- Rheumatoid arthritis.
- Osteoporosis.
- Metabolic disorders.

- Malignancies.
- Paget's disease.
- Osteomyelitis.
- Systemic infection.

6. ADVERSE EVENTS

There were 42 adverse events (AEs) reported during the clinical study in 179 patients at 3 sites. The AEs included bruising, mild edema, pain, swelling, tingling and sprained ankle. There were more AEs in the treatment group versus the sham-control group. None of the AEs was severe, and none required medical intervention or subsequent medical care. A summary of AEs that were observed during treatment with the Orbasone Pain Relief System are shown in Table 1 below:

Table 1 Adverse Events Summary

	Orbasone Group (N=96) n (%)	Sham-Control Group (N=83) n (%)
All Adverse Events	31 (32.3%)‡	11 (13.3%)‡
Bruising	13 (13.5%)	3 (3.6%)
Mild edema	9 (9.4%)	2 (2.4%)
Pain	9 (9.4%)	5 (6.0%)
Swelling	2 (2.1%)	0 (0%)
Tingling	1 (1.0%)	0 (0%)
Sprained ankle	0 (0%)	2 (2.4%)

‡ Some patients may have more than one adverse event.

Other potential adverse events not seen during the study, but observed with other similar devices, include:

- Decreased sensation in the treated foot;
- Petechia;
- Tendon rupture;
- Rare allergic or sensitivity reaction to the latex membrane;

- Hematoma;
- Neural injury or irritation resulting from the local anesthetic injection or shock wave treatment; and
- Anesthesia complication, including allergic reactions to local anesthetic agents.

7. CLINICAL STUDY

A clinical study was conducted to provide data on the safety and effectiveness of the Orbasone Pain Relief System in treating heel pain associated with chronic proximal plantar fasciitis in the U.S.

Study Design and Objectives

This study was a multicenter, randomized, sham-controlled, prospective, double- blind trial consisting of consecutively enrolled patients with foot pain who were randomized to either a group receiving treatment with the Orbasone Pain Relief System or a control group receiving sham treatment. For the sham-control patients, no water was pumped into the reflector head. Although the Orbasone appeared to operate normally, the absence of a transmitting media prevented the shockwave energy from reaching the patient's foot. Subjects were followed for 12 weeks after a single treatment. There were 3 U.S. study sites.

The objectives of this study were to: (1) collect safety and effectiveness data to support a PMA for the Orbasone Pain Relief System; and (2) provide confirming data supporting the safe and effective use of the Orbasone Pain Relief System for the desired indication.

Effectiveness and Safety Endpoints

Primary Endpoint: Subject assessment of pain using a 10 cm Visual Analog Scale ("VAS"). Pain on walking the first few minutes after awakening (within 24 hours of follow-up visit), change from baseline at 3 months (12 weeks) post-treatment.

Secondary Endpoint: Percentage of patients who achieve a 40% reduction from baseline VAS at 3 months post-treatment.

Safety Endpoints: Adverse events and subject complaints; assessment of peripheral neuropathy using Semmes-Weinstein monofilament test, toe clawing; assessment of vascular function using ankle brachial index.

Inclusion and Exclusion Criteria

Inclusion Criteria:

- Male or female greater than 21 years of age.
- Chronic proximal plantar fasciitis that has persisted for at least six months prior to study enrollment as assessed by patient history. The patient has been under the care of a physician for this duration and has been in compliance with a prescribed stretching program.
- Failure to respond to at least four forms of conventional treatment, to include NSAIDs and three other conservative therapies (e.g., physical therapy; use of orthotics; ultrasound; analgesics; corticosteroid injections; shoe modifications; strapping of the foot; and night splints).
- Subject pain self-assessment of ≥6 cm on a 10 cm VAS scale.
- Single site of tenderness with local pressure over the medial calcaneal tuberosity on passive dorsiflexion of the foot.

Exclusion Criteria:

- Previous attempt with any other conservative therapies within two weeks of treatment; corticosteroid injection within one month of treatment.
- Previous surgery for plantar fasciitis.
- Bilateral foot pain.
- Subjects diagnosed with peripheral vascular disease and those with non-palpable pulses of the dorsal pedis or posterior tibial artery underwent testing with a standard Ankle Brachial Index Test ("ABI"). Subjects with ABIs of less than 1.0 were excluded from the study.
- Radiographic evidence of another cause for heel pain (e.g., rheumatoid arthritis; bone cyst or tumor; infection).
- History or documented evidence of:

  autoimmune disease;
  metabolic disorders;
  Type I or Type II diabetes mellitus;
  peripheral neuropathy such as nerve entrapment, tarsal tunnel syndrome;
  systemic inflammatory disease such as rheumatoid arthritis, ankylosing spondylitis, Reiter's syndrome, etc.;
  bleeding disorders or hemophilia;
  known latex allergy;

known sensitivity or allergy to xylocaine; or
calcaneal stress fracture.

- Anticoagulant therapy (including aspirin prophylaxis) within 7 days prior to treatment.
- Patients with implanted defibrillators.
- Patients with prosthetic devices implanted in the area to be treated.
- Treatment area with open wound, skin rash, swelling, or inflammation.
- Active or unresolved infection in the involved foot.
- Pregnancy.
- Patients with pacemakers.

Study Procedures

Following screening, eligible subjects received a single treatment with either the Orbasone Pain Relief System or the sham control. Treatment parameters were: 2000 pulses at 20 to 21 KV at a frequency of 110 pulses/minute. Duration of treatment was 30 to 60 minutes. The total energy density was <1,000 mJ/mm^2. All patients received an injection of up to 10 mL (depending on patient size) of 0.5% bupivacaine into the area of the medial calcaneal branch of the tibial nerve. A summary of the study procedures is provided below in Table 2.

Table 2
Study Procedures

Parameter/Information	Screening/ Pre-treatment	Week 4	Week 8	Week 12
Medical history	√			
Physical exam*	√			
Radiographic evaluation**	√			√
Informed consent	√			
Inclusion/exclusion criteria	√			
Subject self-assessment of pain	√	√	√	√
Medication log	√	√	√	√
Adverse events/ complaints		√	√	√

*Vascular, motor, and sensory function in the treated foot were evaluated at the follow-up visits.
**Pre-treatment radiographs (standard views) were mandatory for every patient screened to rule out any other potential non-plantar fasciitis cause of heel pain. Post-treatment radiographic evaluations will be conducted on an as needed basis.

A health care professional who did not administer the treatment performed the follow-up evaluations and remained masked as to the treatment assignment throughout the follow-up period.

Subjects were permitted to continue their pretreatment program, including stretching, orthotics, night splints, and analgesics after treatment. Use of acetaminophen was permitted as needed for pain. Patients were instructed to discontinue analgesic medication at least 4 half-lives prior to each post-treatment assessment (i.e., 16 hours for acetaminophen).

Study Population

262 patients were screened for this study, and 215 were enrolled. Of these 215 patients, 36 did not return for treatment; therefore, 179 patients were randomized and treated. A total of six patients who were randomized and treated had the following protocol violations, but were included in the intent-to-treat analysis: two patients had a baseline VAS score of <6 cm, and therefore, did not meet the inclusion criterion of a baseline VAS pain score of ≥6 cm, and four patients reported a duration of pain of less than six months prior to enrollment, and therefore, did not meet the inclusion criterion of chronic proximal plantar fasciitis that has persisted for at least six months prior to study enrollment. Of these 179 patients 96 patients were assigned to the active treatment group and 83 were assigned to the sham control group. A summary of patient accountability is provided in Table 3.

Table 3 Patient Accountability

	Orbasone n (%)	Placebo n (%)	Total N (%)
Screened			262
Enrolled			215[a]
Randomized and Treated	96	83	179
Completed	96 (100%)	82 (98.8%)	178 (99.4%)
Terminated Prematurely	0 (0%)	1 (1.2%)	1 (0.6%)
Lost to Follow-up	0 (0%)	1 (1.2%)	1 (0.6%)
Included in primary analysis of effectiveness	96 (100%)	82 (98.8%)	178 (99.4%)
Completed 4 Week Visit	95[b] (99%)	83 (100%)	178 (99.4%)
Completed 8 Week Visit	93[b] (96.9%)	80[b] (96.4%)	173 (96.6%)
Completed 12 WeekVisit	96 (100%)	82[b] (98.8%)	178 (99.4%)

[a] 36 subjects did not return for treatment.
[b] Some subjects did not return for scheduled follow-up visits.

Patient Demographics and Treatment History

Patient demographics and treatment history are summarized in Table 4. There were no significant differences between the treatment and control groups with regard to demographics or treatment history.

Table 4 Patient Demographics

Demographic Variables	Treatment Patients	Control Patients	p-value[a]
Age (years)			Treatment: 0.2654
Mean	49.8	48.5	Site: 0.0041
SE	1	1.3	
Median	51	48.1	
Range	26.1-75	24.9-80.8	
Gender			Treatment: 0.5431
Female	62	49	Site: 0.0913
Male	34	34	
Height (inches)			Treatment: 0.2438
Mean	66.6	67.4	Site: 0.9811
SE	0.5	0.4	
Median	66.5	67	
Range	51-77	60-78	
Weight (pounds)			Treatment: 0.7089
Mean	182.6	183.1	Site: 0.4623
SE	4.3	4.4	
Median	176.5	185	
Range	105-305	100-290	
Affected Foot			Treatment: 0.6292
Right	42	40	Site: 0.2121
Left	51	40	

Duration of Pain (months) Mean SE Median Range	25.3 3.3 14.8 3.2-260.5	34.9 4.2 19.8 6.2-176.3	Treatment: 0.0560 Site: 0.3854
Baseline Pain Score (cm) Mean SE Median Range	7.69 0.11 7.55 5.2-10.1 [b]	7.76 0.12 7.70 5.8-10	Treatment: 0.5774 Site: 0.0882

[a]Kruskal-Wllis test. "Treatment" = difference between Active Treatment and Sham Control; "Site" = Difference across sites.

[b] Patient #45 has a baseline pain score of 10.1,which exceeded the maximum allowable score of 10. This patient is included in all analysis for completeness with the value of 10.1 changed to 10 for analysis.

Effectiveness Results

Primary Endpoint

The primary endpoint for this study is self-reported VAS scores at 4, 8, and 12 weeks after treatment. In addition, a baseline VAS score was obtained at week 0 before treatment. These scores are summarized below in Table 5.

Table 5
VAS Scores for Active and Sham Patients Through 12 Weeks Post Treatment

		Baseline	Week 4	Week 8	Week 12
Active Treatment (cm)	N	96	95	93	96
	Mean	7.69	4.95	3.98	3.11
	SE	0.11	0.26	0.27	0.30
	Median	7.55	5.0	3.70	2.4
	Range	5.2-10.1	0.2-9.9	0.07-10	0-9.8
Sham Control (cm)	N	83	83	80	82
	Mean	7.76	5.94	5.49	5.51
	SE	0.12	0.30	0.32	0.35
	Median	7.70	6.4	6.15	6.5
	Range	5.8-10	0-10	0-10	0-10

The primary analysis of these data is a growth-curve/mixed-effects model. The terms in the model are site, baseline VAS, week, treatment group, treatment group by week interaction and baseline VAS by treatment group interaction. When duration of pain was added to the statistical model, it did not alter the result.

Treatment group effects:

Treatment group, week, and treatment group by week are all significant ($p = 0.0022$, $p < 0.001$, and 0.0002, respectively), which indicates that the treatment group effect changes over the course of the study and should not be viewed as constant over weeks. Control individuals initially reported some decrease in VAS that leveled out, whereas the treatment group starts out with a larger decrease in VAS, which continued to decrease faster than the control group throughout the 12 weeks.

Secondary Endpoint

The secondary endpoint for these data is a yes/no response: Did the subject's VAS score decrease from week 0 to week 12 by 40%? This endpoint was analyzed using a generalized linear model. The effect of treatment group is significant ($p < 0.001$). Table 6 below shows the results by site and treatment group. The treated group has a higher percent of subjects passing this criterion at all sites. There is also a significant site effect ($p = 0.001$) indicating that the differences in these percentages from control to treatment group is variable across sites.

Table 6
Number of Patients Who Achieved a 40% Reduction from Baseline VAS 12 Weeks Post Treatment

	Week 12			
	Site 1	**Site 2**	**Site 3**	**All Sites**
Active Treatment				
No (N)	13	9	6	28
Yes (N)	21	9	38	68
Percent Yes	61.8%	50%	86.4%	70.8%
Sham Control				
No (N)	14	13	25	52
Yes (N)	15	1	14	30
Percent Yes	51.7%	7.1%	35.9%	36.6%

Subjects also were asked what treatment they thought they received after the final (Week 12) visit. In the Active Treatment group, 68/96 (71%) correctly guessed that they received an active treatment, 27/96 (28%) incorrectly guessed that they received the sham treatment, and 1 (1%) was not sure. In the Sham Control group, 43/83 (52%) correctly guessed that they received a sham treatment, 35/83 (42%) incorrectly guessed that they received an active treatment, and (5/83) 6% were not sure. These results indicate that subjects who responded could correctly guess what treatment they received ($p=0.0003$). Review of the comments made by the subjects to support their guesses indicates that their guess was primarily based on the extent of pain relief.

Gender Analysis/Bias

The statistical analysis showed no significant correlation between age, gender, weight, duration of pain, and treatment effectiveness.

Safety Results

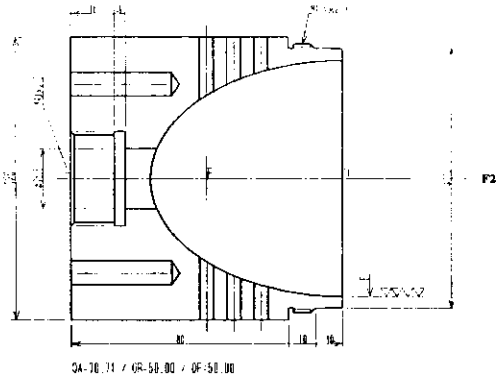
The adverse events are presented in Section 7 above.

The results of the clinical study summarized above provide reasonable assurance that the Orthometrix Orbasone Pain Relief System is safe and effective for patients with symptoms of chronic proximal planter fasciitis of at least 6 months duration who had failed conservative therapy when used in accordance with the device labeling. It should be noted that in order to use the Orbasone Pain Relief System to treat patients, all three investigators were podiatrists and had to complete a special training program. All patients also had to be in compliance with a prescribed stretching program.

8. DEVICE DESCRIPTION

The Orbasone™ Pain Relief System is a device that generates sonic energy wave vibrations and includes:

(1) an ellipsoidal stainless steel focusing reflector;

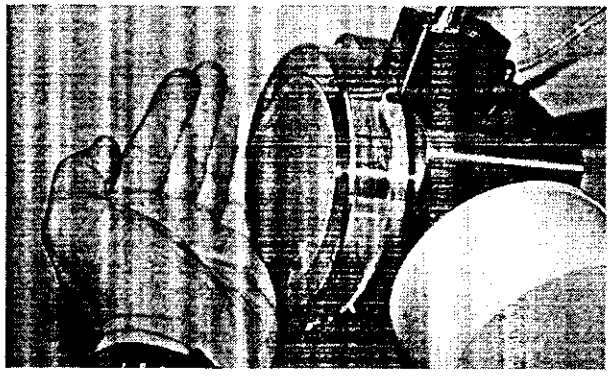


Position: - from original focal point F to target focal point = 102 mm
- from reflector surface [0] to target focal point (F2) = 52 mm

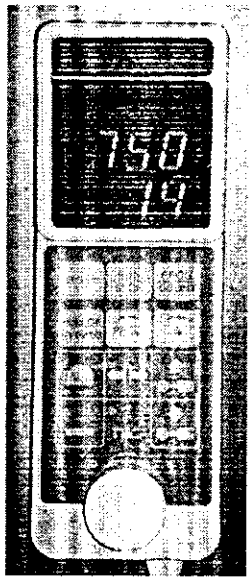
	10 KV	**16KV**	**22KV**
Maximum focal width $f_{x(F2)}$	14.5mm	10.8mm	8mm
Orthogonal focal width $f_{y(F2)}$	10.1mm	7.8mm	6.1mm
Focal extent $f_{z(F2)}$	19.0mm	17.1mm	15.2mm
Peak positive acoustic Pressure (p_+)	64.6 MPa	73.9 MPa	89.1 MPa
Peak negative acoustic pressure (p_-)	3.6 MPa	4.3 MPa	5.4 MPa
Derived Focal acoustic pulse energy	0.26 mJ	0.35 mJ	0.42 mJ

See definitions and diagram on page 49 of 50.

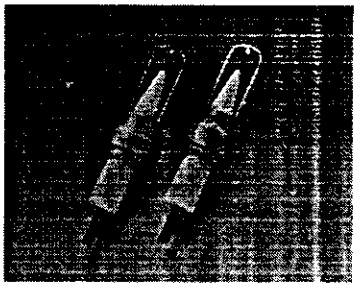
(2) water cushion with coupling membrane;



(3) control hardware; and



(4) energy pulse generator with energy plugs (i.e., spark gap electrodes).



The Orbasone™ Pain Relief System uses a water-filled sphere to reflect and transmit a sonic energy wave to the patient. One half of the sphere is machined from stainless steel, while the other half is formed by a latex membrane. It is the latex membrane that contacts the patient.

The sonic wave is created by a hot bubble of gas formed at the electrode gap in the metal portion of the reflector. The energy plugs are located at the end of the ellipsoid reflector and produce short sparks between the two points. The sparks generate the hot bubble of gas, which expands rapidly, causing a sonic energy wave to be delivered at a point of convergence outside the surface of the latex membrane, no greater than 45 mm under the skin.

The amplitude of the sonic energy wave may be varied by choosing any of twelve (12) power settings, by dialing the knob found on the control panel. During treatment, the sonic waves are delivered at a maximum rate of 110 waves per minute.

Additionally, the total number of sonic energy used is preset and can be as little as 100 to as many as 3000. The control panel has a counter which is set to the desired number of energy waves before treatment begins.

9. WARRANTY:

The Orbasone™ Pain Relief System is warranted by your local distributor against defects in workmanship and materials for a period of one (1) year from the purchase date.

Warranty service may be obtained by contacting the distributor at:

Local distributor:

[To be provided]

Tel: [To be provided]
Fax: [To be provided]

Your local distributor will not cover acts of neglect, abuse, misuse or accidental damage. The warranty is void if the user attempts to service any of the internal parts of the various assemblies supplied as part of the system.

Orthometrix Orbasone

PATIENT INFORMATION

Extracorporeal Shockwave Therapy (ESWT)

A treatment option for Plantar Fasciitis

Orthometrix, Inc.
Corporate Park Drive
White Plains, NY 10604

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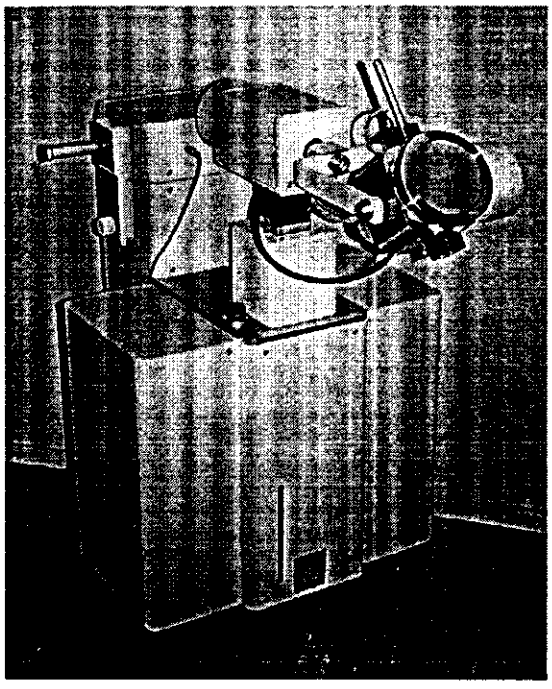
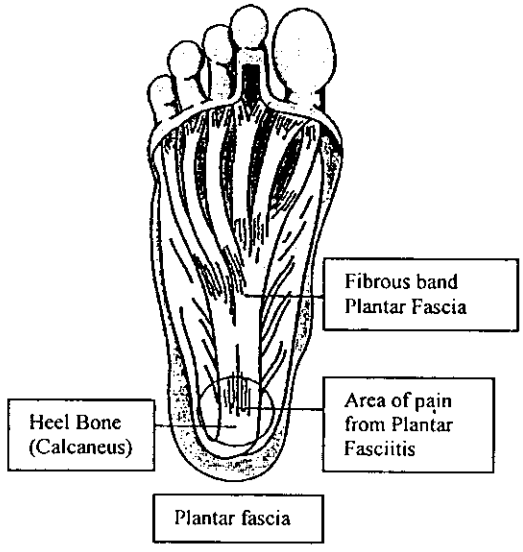


What is extracorporeal shockwave therapy (ESWT)?

The Orbasone is a device that generates shockwaves in a manner similar to systems used to break up kidney stones without surgery. "Extracorporeal" means "outside of the body" and shockwaves are strong pulses of acoustic energy. So, extracorporeal shockwave therapy means that the Orbasone treats heel pain (known medically as plantar fasciitis) by using shock waves (acoustic vibrations) that come from outside of your skin.

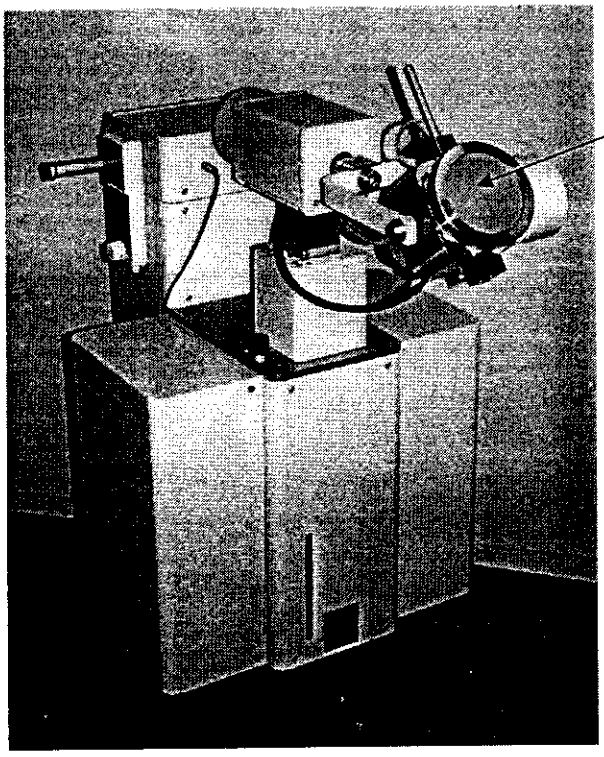
What is plantar fasciitis?

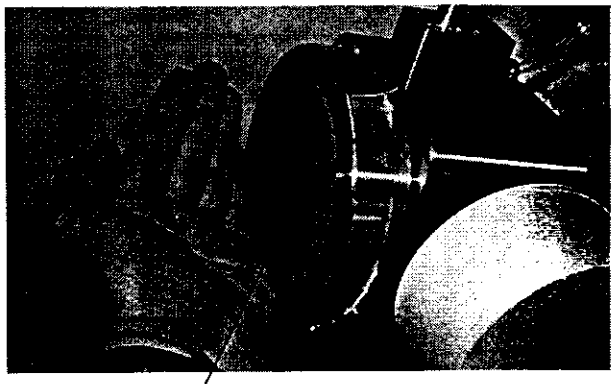
Proximal plantar fasciitis is the inflammation (irritation or injury to tissues) of the plantar fascia. Proximal means nearer to the heel of the foot. The plantar fascia is a tight band of fibrous tissue which begins at the heel, travels across the arch, and ends at the ball of your foot. The inflammation (irritation or injury to tissues) and pain is most often felt at the inner part of the heel and may extend into the arch. The most common symptom is pain after rest, for example, pain when you first rise in the morning. Plantar fasciitis often resolves after conservative care prescribed by your physician. However, extracorporeal shock wave therapy is given to those patients who have chronic pain and who have failed the more conventional or established therapies.



How is the Orbasone procedure performed?

The shockwaves are created by a spark plug that is contained within a soft latex dome filled with water. A charge of electricity is sent to the spark plug, which produces a hot bubble of gas that expands into the surrounding water. It is this expansion of hot gas that creates the shockwave. During the treatment, the dome is placed against the bottom of your heel so the shockwave vibrations can pass through the dome and into your foot.





Shockwave treatments are for patients capable of tolerating sedation and/or local anesthesia. Sedation is given to you through a needle in your arm and makes you feel sleepy, and local anesthesia requires a needle injection in your heel area prior to the treatment. ESWT from the Orbasone is painful and loud. During the treatment procedure, you must wear ear protectors or mufflers to reduce the risk of damaging your hearing.

What are the other treatment options?

Many people with heel pain get better with time, sometimes with no treatment at all. Others get better after trying one or more of the following:

- Rest
- Application of heat
- Physical conditioning exercises
- Heel cushions
- Stretching
- Over-the-counter pain relievers or prescription pain relievers
- Non-steroidal anti-inflammatory medications (NSAID's), such as Advil or Motrin
- Cortisone injections (steroid)
- Taping
- Orthotics
- Nightsplints
- Casting
- Surgery

Who should consider having shockwave treatment for heel pain?

ESWT using the Orbasone is for people who have had proximal plantar fasciitis (heel pain) for at least six months and who have tried other methods for treating their pain that did not work. In the Orbasone clinical study, the participants had failed to respond to at least three attempts at conservative therapies, such as those listed above.

You must be capable of tolerating sedation and/or local anesthesia prior to the procedure and be willing and able to wear hearing protection during the use of the device.

Who should not have a shockwave treatment for heel pain?

You should ***not*** have a shockwave treatment for your heel pain if any of the following apply to you:

- Anyone with open or active bone growth centers until bone growth is complete.
- Anyone with known malignancy in or near the treatment area.
- Anyone with open wounds, skin rashes, swollen, inflamed, or infection in or near the treatment area.
- Anyone with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis may result.
- Anyone taking medications that may prolong or interfere with blood clotting should **not** have an Orbasone treatment.
- Anyone with a history of bleeding problems should **not** have the treatment.
- Anyone with any device implanted in the foot or heel area.
- Children should **not** have a shockwave treatment.
- Pregnant women should **not** have a shockwave treatment.

Additionally, the Orbasone has not been tested on persons who have the following conditions. Its safety and effectiveness are not known for someone with:

- Tarsal tunnel syndrome, or other nerve entrapment disorder (damage or pressure on the nerves to the foot).
- Diabetic neuropathy (nerve damage due to diabetes).
- Fracture of the foot or ankle.
- Significant peripheral vascular disease (circulation problems of the foot and/or leg).
- Severe osteoarthritis.
- Rheumatoid arthritis.
- Osteoporosis.
- Metabolic disorders.
- Malignancies.
- Paget's disease.
- Osteomyelitis.
- Systemic infection.

Your doctor can provide you with additional information about these and other conditions and how they might affect the decision to receive ESWT.

What are the possible side effects or complications to ESWT?

- The shockwave treatment may cause skin reddening or bruising of the treated foot, which usually clears within a few days.
- The Orbasone treatment may cause temporary numbness or tingling in the treated foot.
- The procedure may not help your heel pain, or you may not experience pain relief for a few days or up to several weeks after the treatment. You also may experience some pain from the treatment that could last a few days up to several weeks.
- Mild edema and/or swelling in the foot.
- Local anesthetic or the shockwave treatment may cause nerve damage.
- Local anesthetic may cause an allergic reaction.

What happens on the day of the treatment?

Your doctor will probably ask that you come to the clinic a few hours before the treatment. It is suggested that you wear shorts or loose fitting clothing that can be easily rolled up to the knee. The staff will record your vital functions including: temperature, pulse rate, and blood pressure. They will ask you questions about your general health and have you sign a consent form.

Shockwave treatments are somewhat painful, so an anesthetic will be administered before the session begins. Usually, this will be a local anesthetic or a regional one also called a "nerve block." Additionally, the doctor may offer to sedate you for the procedure. Once the anesthesia and sedation have taken effect, you will be ready for the treatment. You will be asked to rest comfortably on your back while the doctor positions the bottom of your affected foot against the dome of the Orbasone device.

A typical treatment takes between 30 to 45 minutes. The treatment is considered an outpatient procedure, so no overnight stay is needed.

What will happen after the treatment?

Immediately following the procedure, you will stay in the clinic until the anesthetic and sedation (if used) wear off so it is safe for you to walk. You will probably be asked to refrain from stressful physical activities involving the treated foot for 4 weeks after the treatment. Examples of stressful activities include: running, jogging, heavy house or yard work, and participating in sports.

Some patients need mild pain medication after their treatment. Although some people feel immediate pain relief after their shockwave therapy, it is more common for it to take up to 6 weeks for the pain relief to begin.

What are the expected results from shockwave therapy?

In the Orbasone clinical study, subjects with chronic proximal plantar fasciitis were treated with a single session of shockwave therapy with the Orbasone and the results in these subjects were compared to subjects who were "treated" with the Orbasone machine, but the machine did not generate any shockwaves to these subjects (sham control). Pain on walking was measured by the subject using a scale of 1-10 centimeters (cm) called the Visual Analog Scale (VAS). The VAS is a line that allows the subject to indicate the intensity of his/her pain by selecting a location on the line from 1 (indicating no pain) to 10 (indicating worst imaginable pain). The primary endpoint for this study is self-reported pain VAS scores before treatment and at 4, 8, and 12 weeks after treatment.

At 4 weeks post-treatment, there was a statistically significant decrease in self-reported VAS pain scores for subjects in the active treatment group compared to the sham control group. The VAS scores continued to decline at weeks 8 and 12 for the active treatment group, whereas there was no significant change in the VAS scores for the sham control group.

A second endpoint measured in this study was whether or not the subject's VAS score decreased from week 0 to week 12 by 40%. The results of this analysis are shown below in Table 1. Table 1 shows the number of subjects whose pain level was at least 40% lower at 12 weeks (indicated by "yes") after Orbasone treatment or the sham control, and the number of subjects whose pain level was not reduced by at least 40% (indicated by "no") after Orbasone treatment or the sham control.

Table 1
Number of Patients Who Achieved a 40% Reduction from Baseline VAS 12 Weeks Post Treatment

	Week 12
Active Treatment	
No (N)	28
Yes (N)	63
Percent Yes	69.2%
Sham Control	
No (N)	51
Yes (N)	30
Percent Yes	37.0%

Your doctor will ask you to return to the office for a follow-up visit, probably at about 6 or 8 weeks after the treatment. Please check with the doctor about scheduling this follow up visit.

How can I get more information about ESWT?

Talk to your doctor if you have any questions.

In order to use the Orbasone to treat chronic proximal plantar fasciitis, your doctor had to complete a special training program. This program not only prepares the doctor to perform the procedure, but also provides him with information about shockwave therapy in general.

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White Plains, NY
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Extracorporeal Shock Wave Treatment (ESWT) for plantar fasciitis