

EMS

Swiss DolorClast[®]

PHYSICIAN'S LABELING

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

Manufacturer

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1. INTRODUCTION

The EMS Swiss DolorClast® is an extracorporeal shock wave device intended for use in applying shock waves to the heel of patients who have chronic proximal plantar fasciitis and who have failed prior conservative therapies. Shock waves generated by the EMS Swiss DolorClast® propagate radially into the tissue from the point of contact. Thus, the device has no “focusing” characteristics, per se, because the maximum energy is directly at the coupling point on the skin surface, targeting the treatment areas of interest that are close to the skin.

The EMS Swiss DolorClast® is intended to be used by medical professionals who have been trained in its operation.

2. INDICATIONS FOR USE

The EMS Swiss DolorClast® is a non-surgical alternative for the treatment of chronic proximal plantar fasciitis for patients 18 years of age or older with symptoms for 6 months or more and a history of unsuccessful 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.

3. CONTRAINDICATIONS

Use of the EMS Swiss DolorClast® is contraindicated in the following situations:

- Over or near bone growth center until bone growth is complete
- When a malignant disease is known to be present in or near the treatment area
- Infection in the area to be treated
- Over ischemic tissue in individuals with vascular disease
- Patient has a coagulation disorder or is taking anti-coagulant medications
- Patient has a prosthetic device in the area to be treated.

4. WARNINGS

- This EMS Swiss DolorClast® device must be operated by personnel trained in Radial Extracorporeal Shock Wave Therapy
- The EMS Swiss DolorClast® may only be used by qualified and trained persons in medical facilities for its intended purpose.
- Operators of the EMS Swiss DolorClast® should carefully read the Operator Instruction Manual before use.

- Operators of the EMS Swiss DolorClast® should be aware of the proper use of the device in delivering the correct number of impulses and in localizing the proper area to be treated.
- The EMS Swiss DolorClast® handpiece must be carefully positioned and treatment should be performed by a physician trained and experienced in the care of patients with foot and ankle disorders who has been instructed in the operation of the EMS Swiss DolorClast®.
- Avoid treatment over 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, bruising, or hematoma.
- The safety and effectiveness of the EMS Swiss DolorClast® in the treatment of pregnant women, children under the age of 18 years, or patients who have had prior surgery for plantar fasciitis have not been demonstrated. The EMS Swiss DolorClast® is indicated only for patients 18 years of age or older.
- Studies indicate that there are growth plate disturbances in the epiphyses of developing long bones in rats subjected to shockwaves. The significance of these findings in humans is unknown.
- For safety reasons, never connect the handpiece to the housing when the handpiece is not fully assembled. Before assembling/disassembling the handpiece, the quick connector of the connecting tube must be disconnected from the housing; otherwise, there is a potential risk of injury by the projectile in the handpiece if the foot pedal is pressed accidentally.
- This device should not be operated in an explosion hazardous environment.
- To avoid danger of spreading germs and cross contamination of patients it is essential to clean the EMS Swiss DolorClast® before each treatment and sterilize the patient contacting parts if they come in contact with compromised skin.

5. PRECAUTIONS

- Patient pain tolerance is enhanced by starting at a low pressure (i.e., 2 bar) and gradually increasing the pressure to 4 bar over approximately 500 impulses. However, if the patient is not able to tolerate the treatment, then local anesthesia should be administered. Patients who are unable to tolerate local or regional anesthetic or cannot tolerate the treatment pain even with a local or regional anesthetic should not be treated with this device and should consider alternative therapies. All but

one patient treated in the EMS Swiss DolorClast® clinical study were able to tolerate the treatment without anesthesia.

- Although no patients in the clinical study experienced a vaso-vagal reaction during treatment, this reaction has been reported with other types of extracorporeal shock wave therapy. If this reaction occurs, the treatment should be interrupted and the patient reclined to a supine position until symptoms disappear.
- The housing of the EMS Swiss DolorClast® is not watertight. The handpiece is neither watertight nor autoclavable and should not be immersed into liquids nor chemically disinfected.
- The safety and effectiveness of the EMS Swiss DolorClast® to treat painful heel has not been established for patients with the following conditions:
 - Under 18 years of age
 - Diseases or disorders of the nerves in the foot to be treated
 - Diseases or disorders of the bones in the foot to be treated
 - Infection in the area to be treated
 - Current or recent therapy that would compromise tissue healing
 - Problems with circulation or bleeding
 - History or documented evidence of immune system deficiencies (autoimmune disease)
 - Significant disease of the blood vessels in the foot to be treated
 - Rheumatoid arthritis (pain, stiffness or swelling of the joints)
 - Malignant disease with or without metastases in heel
 - Previous treatment of the painful heel with corticosteroid injections within 6 weeks of the EMS Swiss DolorClast® treatment or previous treatment with non-steroidal anti-inflammatory drugs within 1 week of the EMS Swiss DolorClast® treatment
 - Previous surgery for painful heel
 - Pregnant female

6. ADVERSE EVENTS

During the EMS Swiss DolorClast® clinical study, a total of 73 non-serious adverse events were reported during the 12 week follow-up period in 41 of the 129 patients (31.8%) receiving active treatment. Of these reports, 23 adverse events in 16 patients were considered to be not device related and 50 adverse events in 33 patients were considered to be device related. Eight patients reported both device related and non-device related adverse events.

In the placebo group, a total of 36 adverse events were reported in 27 of the 122 patients (22.1%) during the 12-week follow-up period. Of these reports, 25 adverse events in 19 patients were considered to be not device related, and 11 adverse events in 10 patients were considered to be device related. Two of these patients reported both device related and non-device related adverse events.

Table 1 summarizes the adverse events that were considered to be related to the device. The most common adverse event associated with use of the EMS Swiss DolorClast® is pain or discomfort during treatment. This side effect was noted by 23% of the patients treated with the EMS Swiss DolorClast® in the clinical study, but all patients except for one were able to complete their treatments without any anesthesia. In the majority of cases the duration of treatment pain was reported to be a maximum of less than 10 minutes

Table 1: Summary of Device Related Adverse Events, Safety Population (n=251) at 12-week follow-up

Event	ESWT Group (N=129)			Placebo Group (N=122)		
	# Events	# Subjects	% Total Subjects	# Events	# Subjects	% Total Subjects
Pain or discomfort during treatment	43	30 ¹	23.26%	5	5	4.10%
Pain post-treatment	5	5 ²	3.88%	3	3	2.46%
Skin reddening	1	1 ³	0.78%	1	1	0.82%
Swelling and pain post-treatment	1	1	0.78%	1	1	0.82%
Numbness post-treatment	0	0	0%	1	1	0.82%

¹Twenty subjects with pain during one treatment session, seven during two sessions, and three during three sessions

²Three subjects also reported pain during treatment.

³This subject also reported pain during treatment.

In the active ESWT treated group, a total of 23 non-device related adverse events were reported in 16 of the 129 patients (12.4%). These were as follows: wasp sting (1), common cold disease (3), cough (1), sinusitis (2), headache (6), body aches (1), pain of the hip (1), toe (1) or

neck (1), intermittent back pain of unknown etiology (1), aggravated neuroma (1), tinnitus (1), occasional knee weakness due to knee injury (1), developing tendonitis (1), and heart murmur (1).

In the placebo group, there were a total of 25 non-device related adverse events reported in 19 of the 122 patients (15.6%). These reports were as follows: gastric ulcer (1), upset stomach (2), irregular heart "movement" (1), pain long after treatment end in heel(1)/right shoulder (1)/body aches (1), infection of nose, ear and throat (1), fracture of the toe (right foot) (1), pain and swelling of left knee (1), acute nausea (1), adductor-strain (1), headache (10), common cold disease (2) and congestion (1). Only six additional adverse events in five patients (1 in the active ESWT treated group and four in the placebo group) were reported during the 6-month and 12-month follow-up period. All of these reports were considered to be not related to the device. There was one report of ischiatic pain plus lumbar back pain in one patient in the active ESWT treated group. There were five non-device related adverse event reports in four patients in the placebo treated group. These were as follows: lateral right foot pain along metatarsus (1), acute nausea (1), teeth inflammation (1), zoster neuralgia (1), and umbilical hernia (1).

Other potential adverse events that have not been observed in clinical studies of the EMS Swiss DolorClast® may include:

- Bruising
- Rupture of the plantar fascia (tissue along the bottom of the foot)
- Temporary or permanent damage to the blood vessels
- Petechia
- Temporary or permanent nerve damage causing hypesthesia or parasthesia
- Hematoma
- Tendon rupture

7. CLINICAL STUDY

A multi-center, randomized, placebo-controlled, prospective, double-blind clinical study was conducted with two groups: a group receiving radial ESWT with the EMS Swiss DolorClast® and a control group receiving a sham treatment. A total of 251 patients, randomized in a 1:1 allocation ratio, were treated at eight clinical sites. For the purpose of this study, chronic proximal plantar fasciitis was defined as painful tenderness localized at the inferomedial aspect of the calcaneal tuberosity close to the insertion area of the plantar fascia that had persisted for at least six months prior to study enrollment.

7.1 Subject Eligibility

The eligibility criteria described in the study protocol were as follows:

Inclusion Criteria

All of the following criteria have to be met for inclusion of a subject into the study:

1. Age greater than 18 years,
2. Ability of subject or legal respondent to give written informed consent after being told of the potential benefits and risks of participating in the study,
3. Signed informed consent,
4. Diagnosis of painful heel syndrome (i.e., chronic proximal plantar fasciitis) proven by clinical examination,
5. 6 months of unsuccessful conservative treatment i.e., must have undergone at least 2 unsuccessful non-pharmacological treatments and at least 2 unsuccessful pharmacological treatments. The following conservative treatments may have been completed as single, combined or consecutive treatments:

Non-pharmacological treatments

- Physical therapy e.g., ice, heat or ultrasound
- Physiotherapy e.g., massage and stretching
- OTC-devices like orthosis, taping and heel pads
- Prescribed orthosis
- Shoe modification like higher heels
- Cast/immobilization
- Night splints

Pharmacological treatments

- External (topical) application of analgesics and/or anti-inflammatory gels
- Therapy with prescription analgesic or NSAIDs
- Local anesthetic injections
- Local corticosteroid injections

6. Time gap of at least:
 - 6 weeks since the last cortisone injection;
 - 4 weeks since the last iontophoresis, ultrasound and electromyostimulation;
 - 1 week since the last NSAIDs and
 - 2 days since the last analgesics, heat, ice, massage, stretching, night splinting and orthosis
7. Scores of ≥ 5 on both VAS pain scales (heel pain when taking first steps of the day and heel pain while doing daily activities)
8. Willingness to refrain from the following painful heel related, concomitant therapies: iontophoresis; electromyostimulation; ultrasound; NSAIDs; steroid injections or surgery – Until Visit 7 of this study (shoe modifications and rescue pain medication are allowed during the entire study)
9. Willingness to keep a Subject Heel Pain Medication and Other Heel Pain Therapy Diary until 12 months after the last treatment,
10. Females of childbearing potential may be entered if they provide a negative urine pregnancy test immediately before the first ESWT treatment
11. Willingness of females of childbearing potential to use contraceptive measures for 2 months after enrollment into the study

Exclusion Criteria

Any of the following excludes a subject from the study:

1. Subjects suffering from tendon rupture, neurological or vascular insufficiencies of the painful heel;
2. Inflammation of the lower and upper ankle;
3. History of rheumatic diseases, and/or collagenosis and/or metabolic disorders;
4. Subjects with a history of hyperthyroidism;
5. Malignant disease with or without metastases;
6. Subjects suffering from Paget disease or calcaneal fat pad atrophy;
7. Subjects suffering from Osteomyelitis (acute, sub acute, chronic);
8. Subjects suffering from fracture of the Calcaneus;
9. Subjects with an immunosuppressive therapy;
10. Subjects with a long-term-treatment with corticosteroid;
11. Subjects suffering from diabetes mellitus, severe cardiac or respiratory disease;
12. Subjects suffering from coagulation disturbance and/or therapy with Phenprocoumon, Acetylsalicylic acid or Warfarin;
13. Bilateral painful heel, if both feet need medical treatment;
14. Subjects who, at entry, are known to have treatment planned within the next 8 weeks, which may abruptly alter the degree or nature of pain experienced such that the radial extracorporeal shock wave therapy will no longer be necessary (e.g., surgery);
15. Time gap of less than:
 - 6 weeks since the last cortisone injection;

- 4 weeks since the last iontophoresis, ultrasound and electromyostimulation;
 - 1 week since the last NSAIDs and
 - 2 days since the last analgesics, heat, ice, massage, stretching, night splinting and orthosis;
16. Previous surgery of the painful heel syndrome;
 17. Previous unsuccessful treatment of the painful heel with a similar shock wave device;
 18. History of allergy or hypersensitivity to bupivacaine or local anesthetic sprays;
 19. Subjects with significant abnormalities in hepatic function;
 20. Subjects in a poor physical condition;
 21. Pregnant female;
 22. Infection in the treatment area recently or in medical history;
 23. History or documented evidence of peripheral neuropathy such as nerve entrapment, tarsal tunnel syndrome, etc.;
 24. History or documented evidence of systemic inflammatory disease such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, aseptic bone necrosis, Reiter's syndrome, etc.;
 25. History or documented evidence of worker's compensation or litigation;
 26. Participation in an investigational device study within 30 days prior to selection, or current inclusion in any other clinical study or research project;
 27. Subjects who, in the opinion of the investigator, will be inappropriate for inclusion into this clinical study or will not comply with the requirements of the study.

7.2 Study Design

Subjects who signed the study informed consent form and met the study eligibility criteria were randomized to receive either the active or placebo device treatment in a 1:1 allocation, but were not told of their randomization assignment. The placebo handpiece and applicator were constructed so that the pressure impulse was blocked from being transferred to the treatment site, but otherwise was the same as the active handpiece and applicator in terms of sound, vibration and appearance.

After a screening visit to determine eligibility (Visit 1), the study started at Visit 2 with the first treatment (after randomization). The treatment protocol was the same for active and placebo subjects. The protocol specified up to 2500 impulses at each of three visits (V2, V3 and V4), spaced 2 weeks apart. The first 500 shocks were applied at gradually increasing pressure (from 2 to 4 bar) in order to desensitize the patient to the pain of the impulses. After the 500 introductory impulses, 2000 treatment impulses were performed at a pressure of 4 bar. If the patient could not tolerate the pain during the first 250 introductory impulses, the investigator was allowed to perform a local anesthesia in these subjects using 5-10 ml of 0.5% bupivacaine in a medial application or a local anesthetic spray.

The follow-up period began 1 week after the last treatment (Visit 5, 5 weeks after randomization). Follow-up evaluations were performed by study investigators who were not involved in the subject's treatment and were blinded as to the subject's randomization. Follow-up visits continued at 6 weeks (Visit 6), and 12 weeks (Visit 7) following the last treatment (or 10 weeks and 16 weeks following randomization, respectively). Patients who had sufficient pain relief to meet the study definition of "responders" continued in the study at this point and were followed again at 6 months (Visit 8) and 12 months (Visit 9) following the last treatment. A "responder" was defined in the study protocol as a subject with at least 60 percent reduction in pain when taking first steps of the day and while doing daily activities or, if less than 60 percent reduction on the above, then the subject was satisfied with the outcome of the treatment, was able to work (if applicable) and did not require concomitant therapy to control heel pain.

7.3 Study Population

A total of 251 subjects formed the Safety Population for the study: 152 in five German centers and 99 in three US centers. Of these, 129 were randomized to the active group and 122 to the placebo group. Ninety-seven percent of this patient population (243/251) received at least one treatment and had at least one follow-up evaluation, and formed the core patient population for efficacy analysis (Intent to Treat population, ITT). Of these 243 patients, 125 were in the ESWT group and 118 were in the placebo group. Eighty-seven percent of the Safety Population had all three treatments and completed all follow-up visits through Visit 7 (Per Protocol population, PP). Of the 219 Per Protocol patients, 111 were in the ESWT group and 108 were in the placebo group.

Analysis of the subject baseline characteristics and demographic data for the ITT patient population demonstrate that the ESWT and placebo groups were well comparable at baseline on all variables and all p-values were statistically not significant ($p > 0.1$).

7.4 Treatment Information

The majority of subjects in the Safety Population completed all three treatment sessions 90.7% (117/129) ESWT and 95.9% (117/122) placebo. The average number of impulses delivered per treatment session ranged between 2413 and 2451 and was very similar between the two treatment groups (p -value >0.5 for all treatment sessions). Placebo impulses were blocked from reaching the treatment area. Although 30 ESWT and 5 placebo subjects complained of pain during treatment, only one subject requested local anesthesia for the pain. Only one device malfunction was reported during the study (placebo applicator did not function and treatment was conducted with a second applicator). No subject in either group experienced an adverse event as a result of a device malfunction.

7.5 Primary Efficacy Results

The primary efficacy endpoint was a composite of three measures of chronic proximal plantar fasciitis, evaluated using a 10 cm Visual Analog Scale (VAS): heel pain upon taking first steps of the day, heel pain while doing daily activities, and heel pain after application of the Dolormeter (a standardized pressure device). The composite result was calculated two ways, first on a continuous scale as the sum score of the three measurements and second on a binary scale (success/failure) with success being defined as greater than 60 percent reduction in VAS score from baseline to Visit 7 (12 weeks after the last ESWT treatment) on at least two of the three heel pain measurements.

The primary timepoint for evaluating the efficacy of the treatments was at Visit 7, or 12 weeks following the third treatment session. Results are presented in Tables 2 and 3 for both the Intent-to-treat (ITT) population (subjects who completed at least one treatment session and one evaluation session) and the Per Protocol population (subjects who completed all three treatment sessions and all follow-up evaluations). Missing data was handled using the Last Value Carried Forward (LVCF) approach. Pain scores were adjusted for subjects who took interfering analgesics or had other therapies for their painful heel within predefined timeframes prior to evaluation visits by adding 2 points to their VAS scores for the affected visit. EMS conducted supportive sensitivity analyses to confirm the results obtained using these methods.

Table 2: Primary Efficacy Results for ITT Population at Visit 7 - Composite Scores for Three VAS Measures

	Swiss DolorClast (N _{ITT} =125)	Placebo (N _{ITT} =118)	Effect Size ¹	P-Value One Sided
Composite VAS Score: Percent Change from Baseline at Visit 7				
Mean (SD)	-56.0 (39.31)	-44.1 (41.81)		
Median	-72.1	-44.7	0.5753	0.0220 ²
Overall Success Rate (>60% reduction in VAS on at least two pain measures)	60.98% (75/123)	42.24% (49/116)	0.5937	0.0020 ³

¹Mann-Whitney (MW) effect size

²Wilcoxon-Mann-Whitney test

³Unconditional Exact Röhmel-Mansman test

Table 3: Primary Efficacy Results for Per Protocol Population at Visit 7 - Composite Scores for Three VAS Measures

	Swiss DolorClast (N _{pp} =111)	Placebo (N _{pp} =108)	Effect Size ¹	P-Value One sided
Composite VAS Score: Percent Change from Baseline at Visit 7				
Mean (SD)	-60.6 (35.97)	-44.2 (42.11)	0.6037	0.0041 ²
Median	-75.0	-44.3		
Overall Success Rate (>60% reduction in VAS on at least two pain measures)	64.55% (71/110)	43.40% (46/106)	0.5788	0.0011 ³

¹Mann-Whitney (MW) effect size

²Wilcoxon-Mann-Whitney test

³Unconditional Exact Röhmel-Mansman test

The primary efficacy results for the ITT population demonstrate that the mean composite pain score for the ESWT group (sum of VAS scores for the three pain measures) decreased from 22.0 ± 3.24 at baseline to 9.7 ± 8.56 at Visit 7, for a mean percent decrease (i.e., improvement) of 56 percent. In the placebo group, the mean composite pain score decreased from 21.6 ± 3.22 at baseline to 12.3 ± 9.39 at Visit 7, for a mean percent decrease of 44 percent. These results show a significant improvement in the mean composite VAS score for the ESWT group as compared to the placebo group ($p=0.022$).

The result for overall success rate, defined as greater than a 60 percent reduction in VAS pain scores on at least two of the three pain measures, was also superior for the ESWT group as compared to the placebo group. Sixty-one percent (75/123) of the ESWT subjects met this success criterion as compared to 42 percent (49/116) of the placebo subjects group ($p=0.002$).

The results for the Per Protocol population further support the efficacy of ESWT with the EMS Swiss DolorClast[®]. In this population, where all subjects received the full prescribed three treatments, the results for the ESWT group improved (as compared to the ITT population) while the results for the placebo group stayed essentially the same (as compared to the ITT population). The superiority of the Per Protocol ESWT group as compared to the Per Protocol placebo group is confirmed by this analysis ($p<0.01$ on both composite VAS score and overall success).

7.6 Secondary Efficacy Results

The secondary efficacy criteria included the Roles and Maudsley Score, SF-36 Quality of Life evaluation, investigator's global judgment of effectiveness, subject's satisfaction with their therapy outcome, and whether the subjects

would recommend the EMS Swiss DolorClast® therapy to a friend. Results are summarized in Table 4. The ESWT group demonstrated greater improvements from baseline to Visit 7 on all secondary measures as compared to the placebo group ($P < 0.025$ one-sided).

Table 4: Secondary Efficacy Results for ITT Population

	Swiss DolorClast (N _{ITT} =125)	Placebo (n _{ITT} =118)	Effect Size ²	P-Value One Sided
Roles and Maudsley Score				
Excellent or Good	58.40% (73/125)	41.52% (49/118)	0.5973	0.0031 ³
Fair or Poor	41.60% (52/125)	58.48% (69/118)		
SF-36 Physical¹				
Percent Change from Baseline at Visit 7				
Mean / SD	-37.2 (48.42)	-19.5 (52.13)	0.6191	0.0013 ³
Median	-44.1	-23.9		
SF-36 Mental¹				
Percent Change from Baseline at Visit 7				
Mean / SD	-14.6 (62.89)	+8.4 (99.06)	0.5850	0.0163 ³
Median	-22.8	-14.3		
Investigator Judgment of Effectiveness				
Very good or Good	70.80% (80/113)	40.91% (45/110)	0.6335	0.0002 ³
Moderate	10.62% (12/113)	20.91% (23/110)		
Unsatisfactory or Poor	18.58% (21/113)	38.18% (42/110)		
Patient Judgment of Therapy Satisfaction				
Very or Moderately Satisfied	63.16% (72/114)	46.36% (51/110)	0.5984	0.0045 ³
Slightly Satisfied or Neutral	18.42% (21/114)	10.00% (11/110)		
Dissatisfied	18.42% (21/114)	43.64% (48/110)		

¹SF-36 scores standardized using a scale from 0 (best score) to 100 (worst score); negative percent change from baseline indicates improvement.

²Mann-Whitney (MW) effect size.

³p-values of one-sided test for superiority using the Wilcoxon-Mann-Whitney test

7.7 Follow-up Results at 6-Months and 12-Months

Treatment Responders at Visit 7 continued in the study and returned for two additional follow-up visits, Visit 8 at 6 months following the last treatment and Visit 9 at 12 months following the last treatment. The evaluations/procedures conducted at Visit 8 were the same as conducted at Visits 5 and 6, while the evaluations/procedures conducted at Visit 9 were the same as conducted at Visit 7. Subject Diaries for Responders were collected at Visit 9.

Results at both the 6-month and 12-month follow-up visits were similar to the results presented above for visit 7. Results at the 12-month follow-up (Visit 9) are shown in Table 5 below for the ITT population. Results include the composite scores and overall success rate in accordance with the same criteria used for the primary efficacy results at Visit 7. Missing data was handled using the Last Value Carried Forward (LVCF) approach. Pain scores were adjusted for subjects who took interfering analgesics or had other therapies for chronic proximal plantar fasciitis within predefined timeframes prior to evaluation visits by adding 2 points to their VAS scores for the affected visit.

In both the EMS Swiss DolorClast® ESWT group and the placebo group, the mean composite scores increased slightly from the scores at Visit 7. The results continue to show an improvement in the mean composite VAS score for the ESWT group as compared to the placebo group. Likewise, the overall success rate (defined as greater than 60 percent reduction in VAS pain scores on at least two of the three pain measures) for the ESWT group continued to be superior to that of the placebo group. These results confirm that the results obtained at the 3-month primary efficacy endpoint are maintained over a period of up to 12 months.

Only six additional adverse events in five patients were reported during the 6-month and 12-month follow-up period (one patient in the ESWT group and four patients in the placebo group). None of these reported adverse events were considered to be related to the device.

Table 5: Efficacy Results for ITT Population at Visit 9 (12-months) - Composite Scores for Three VAS Measures

	Swiss DolorClast (N _{ITT} =125)	Placebo (N _{ITT} =118)
Composite VAS Score: Percent Change from Baseline at Visit 9		
Mean (SD)	-61.9(43.62)	-46.5 (45.52)
Median	-84.8	-43.2
Overall Success Rate (>60% reduction in VAS on at least two pain measures)	63.41% (78/123)	43.97% (51/116)

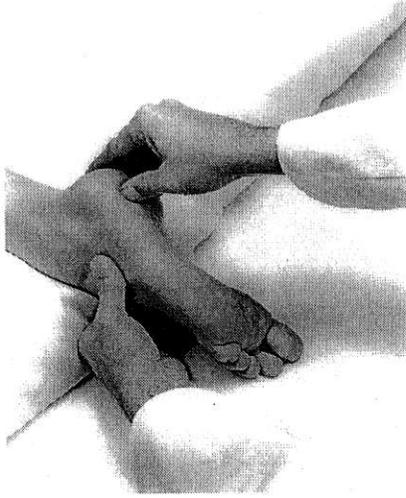
7.8 Safety Results

See Section 6.0 above for adverse events reported during the study.

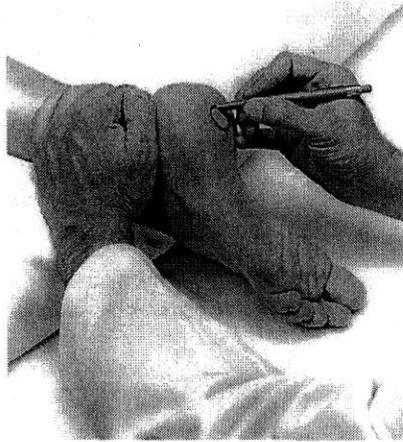
7.9 Conclusions

The results of the clinical study summarized above provide reasonable assurance that the EMS Swiss DolorClast® is safe and effective when used in accordance with the device labeling. The results of the multi-center, randomized, placebo-controlled, double-blinded clinical study demonstrate that treatment with the EMS Swiss DolorClast® provides relief to patients with symptoms of proximal plantar fasciitis of at least 6 months duration who had failed previous conservative therapy.

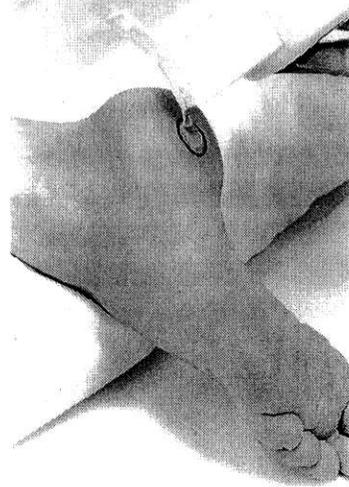
8.0 TREATMENT OF CHRONIC PROXIMAL PLANTAR FASCIITIS



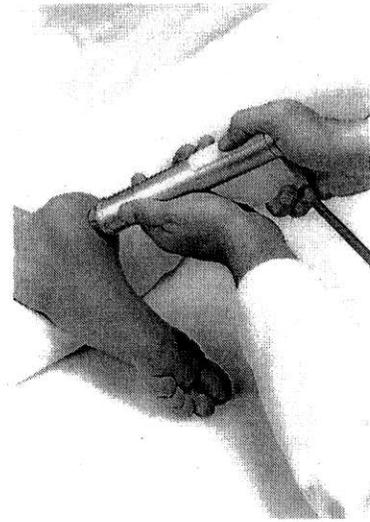
1. The treatment site is located using palpation and patient feedback regarding the area of pain.



2. After locating the treatment site, the skin of the treatment area is marked.
3. Local anesthesia, if necessary, should be by subcutaneous injection or anesthesia spray. Do not inject directly into the treatment site.



4. Use EMS Swiss DolorClast[®] coupling gel for improved coupling.



5. Gently rub the applicator tip over the site of treatment in multiple impulse mode. Exert as much pressure as the patient can reasonably tolerate (use the Ø15 mm applicator).

EMS
Swiss DolorClast[®]

**For Treatment of Chronic Proximal
Plantar Fasciitis (Painful Heel
Syndrome)**

Patient Information

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Manufacturer

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Regulatory Statement for the United States

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

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1. WHAT IS THE EMS SWISS DOLORCLAST®?

The EMS Swiss DolorClast®, illustrated in Figure 1, is an extracorporeal shock wave therapy device intended for use in treating chronic proximal plantar fasciitis (painful heel). Proximal means near to the heel. The therapeutic shock waves (high intensity sound waves) are delivered from outside of the body (i.e., "extracorporeally"), so the treatment is completely non-invasive.

The device consists of a control unit and a handpiece, with the treatment applicator mounted on the end of the handpiece. The treatment applicator is held in contact with the heel at the point of maximum tenderness as illustrated in Figure 2. Compressed air is used to drive a projectile (metal cylinder) within the handpiece toward the applicator. When the projectile hits the applicator inside the handpiece, a shock wave is generated (high intensity sound wave) that is then transferred to the treatment site. The highest energy density will be at the point of contact of the applicator (the treatment site), but the shock wave will travel outward (i.e., radially) into the soft tissue surrounding the point of contact.

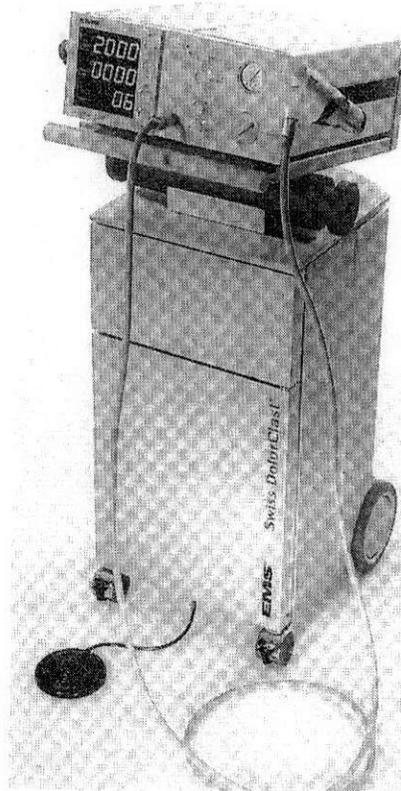


Figure 1. EMS Swiss DolorClast®

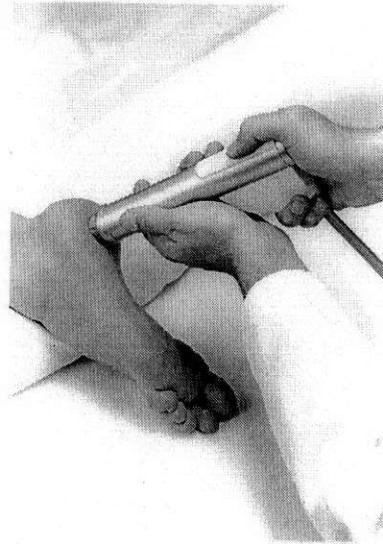


Figure 2. Handpiece and Treatment Applicator In Place for Treatment of Plantar Heel Pain

2. WHAT IS CHRONIC PROXIMAL PLANTAR FASCIITIS?

Chronic proximal plantar fasciitis, also called painful heel syndrome, is a condition in which there is painful tenderness in the area around the medial (middle part) plantar calcaneal tuberosity (heel bone). See Figure 3 below:

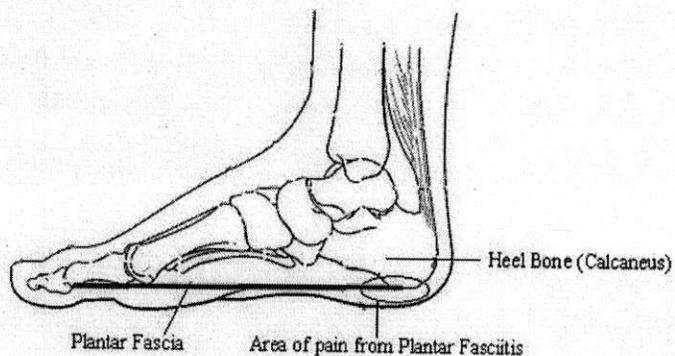


Figure 3: Location of Heel Pain

3. WHO SHOULD HAVE TREATMENT WITH THE EMS SWISS DOLORCLAST®?

The EMS Swiss DolorClast® is intended to apply shock waves to the heel for the treatment of chronic proximal plantar fasciitis (painful heel syndrome). It is intended to be used for patients who are 18 years of age or older who have symptoms of painful heel syndrome that have lasted for 6 months or more and who have tried other conservative therapies but without success.

4. WHO SHOULD NOT HAVE TREATMENT WITH THE EMS SWISS DOLORCLAST®?

Treatment with the EMS Swiss DolorClast® should not be performed if any of the following conditions exist:

- You have incomplete bone growth over or near the area to be treated
- There is malignant disease (cancer) in or near the treatment area
- You have an infection in the area to be treated.
- You have ischemic tissues (tissues that have poor blood circulation) at the treatment site
- If you have a coagulation (bleeding) disorder or if you are taking anti-coagulation medications
- You have a prosthetic device in the area to be treated.

In addition, if you have any of the conditions listed in Section 5 below you should consult with your doctor to determine if this therapy is appropriate for you.

5. WHAT ARE THE PRECAUTIONS ABOUT THIS TREATMENT?

The safety and effectiveness of the EMS Swiss DolorClast® for treatment of painful heel has not been established for patients with the following conditions:

- Under 18 years of age
- Diseases or disorders of the nerves in the foot to be treated
- Diseases or disorders of the bones in the foot to be treated
- Infection in the area to be treated
- Current or recent therapy that would compromise tissue healing
- Problems with circulation or bleeding disorders
- History or documented evidence of immune system deficiencies (autoimmune disease)
- Disease of the blood vessels in the foot to be treated
- Rheumatoid arthritis (pain, stiffness or swelling of the joints)
- Malignant disease (cancer) in any part of the body, including the heel
- Previous treatment of the painful heel with corticosteroid (steroid) injections within 6 weeks of the EMS Swiss DolorClast® treatment or previous treatment with non-steroidal anti-inflammatory drugs (such as ibuprofen) within 1 week of the EMS Swiss DolorClast® treatment
- Previous surgery for painful heel
- Pregnant female

If you have any of the above conditions you should consult with your doctor to determine if this treatment is appropriate for you.

6. WHAT ARE THE RISKS OF THE TREATMENT

The most likely risk associated with use of the EMS Swiss DolorClast[®] is pain or discomfort during treatment. This side effect was noted by 23% of the patients treated with the EMS Swiss DolorClast[®] in a clinical study, but all patients except for one were able to complete their treatments without any anesthesia. Other adverse events associated with use of the EMS Swiss DolorClast[®] that were reported during the study were continued pain after treatment (in 3.9% of patients), skin reddening after treatment (in less than 1 percent of patients), and swelling with pain after treatment (in less than 1 percent of patients).

Other potential adverse events that have not been observed in clinical studies of the EMS Swiss DolorClast[®] may include:

- Bruising
- Rupture of tissue along the bottom of the foot (plantar fascia)
- Temporary or permanent damage to the blood vessels
- Petechia (small reddish or purple spots on the skin)
- Temporary or permanent nerve damage causing loss of feeling
- Hematoma
- Tendon rupture

During the clinical study, a total of 23 other adverse events that were not believed to be related to the EMS Swiss DolorClast[®] were reported in 16 of the 129 patients who were treated with the EMS Swiss DolorClast[®] (12.4%). These were as follows: wasp sting (1), common cold disease (3), cough (1), sinusitis (2), headache (6), body aches (1), pain of the hip (1), toe (1) or neck (1), intermittent back pain of unknown etiology (1), aggravated neuroma (1), tinnitus (1), occasional knee weakness due to knee injury (1), developing tendonitis (1), and heart murmur (1).

Your doctor will be able to discuss all of the potential risks of the treatment with you. Make sure that you tell your doctor if you experience any side effects during or following treatment of your painful heel with the EMS Swiss DolorClast[®].

7. WHAT ARE THE POTENTIAL BENEFITS OF THE TREATMENT?

This therapy may relieve the pain in your heel and it might eliminate the need for surgery. However, it is possible that the therapy may not completely eliminate your pain or it may not work at all. A clinical study of the EMS Swiss DolorClast[®] demonstrated that the treatment is both safe and effective in relieving heel pain in some patients who had suffered from painful heel for at least 6 months and had failed numerous conservative therapies prior to radial extracorporeal shock wave therapy. The treatment was considered to be successful in 61 percent of the patients who were treated with the EMS Swiss Dolorclast[®], while only 42 percent of patients who received a “sham” (simulated) treatment were considered to be successes. A treatment was considered to be “successful” if the patient reported that his/her pain was improved by 60 percent or more on two out of three different tests (see details of the clinical study below).

8. WHAT ARE THE ALTERNATIVE TREATMENTS?

Heel pain is generally treated conservatively with a variety of drug and non-drug therapies, including the following:

- Over-the-counter or prescription pain medication or non-steroidal anti-inflammatory agents (NSAIDs, e.g., Ibuprofen)
- Injections of anesthetics around the painful heel
- Corticosteroid (steroid) injections around the painful site
- Physical therapy (i.e., ice, heat, ultrasound)
- Physiotherapy (i.e., massage, stretching)
- Orthotics, heel pads, and shoe modifications
- Taping, night splints, immobilization, or casting

Prior to treatment with the EMS Swiss DolorClast[®], you should have tried and failed a variety of these other conservative therapies over a period of at least 6 months. Talk with your doctor about the most appropriate alternative therapies for your painful heel.

9. HOW IS TREATMENT WITH THE EMS SWISS DOLORCLAST® PERFORMED?

If your doctor determines that treatment with the EMS Swiss DolorClast® is appropriate for your painful heel, you will be placed in prone position and your doctor will palpate your heel to locate the tenderest position. Your feedback to your doctor will be important to locate the center of your pain. Coupling gel will be applied to your heel and the treatment applicator will be held in contact with your heel at this location.

When the treatment begins, the impulses will be delivered at a low pressure and slowly increased to the target treatment pressure (4 bar). This should allow you to get used to the moderate treatment pain so that you should not need any anesthesia to complete the treatment. However, if you do experience pain that you cannot tolerate, you should tell your doctor who can then administer a local anesthesia (using a shot or an anesthesia spray). Once the treatment pressure of 4 bar is reached, treatment will continue until a total of 2000 impulses at 4 bar have been delivered.

You will be expected to undergo a total of three treatment sessions within 2 weeks in order to realize the maximum benefits of the treatment. Your doctor may also want you to return for short follow-up visits to assess your response to the treatments. You should notice a gradual improvement in your heel pain over time, and it may take up to 3 months before you notice significant improvement. Be sure to tell your doctor about any changes in your heel pain and any side effects you experience from the treatment.

10. WHAT ARE THE RESULTS OF THE CLINICAL STUDY?

A clinical study using the EMS Swiss DolorClast® to treat painful heel was conducted at eight hospitals or medical centers: three in the United States and five in Germany. A total of 251 subjects were treated in the study. Half of the subjects received treatment with an active device and half with a sham device. The sham device looks and sounds like the active one, but did not emit any impulses to the heel. All subjects were blinded, that is, they did not know whether they had received the active or sham treatment. All subjects in the study had symptoms of painful heel for at least 6 months that had not responded to prior conservative therapies.

Before starting the treatment, all subjects underwent testing to establish the level of their pain using a Visual Analog Scale (VAS, a line to indicate pain level, with 0 equal to no pain and 10 equal to unbearable pain). To qualify for the study, subjects had to have levels of at least 5 out of 10 for heel pain when taking the first steps in the morning and heel pain during daily activities. Subjects were also asked to evaluate their heel pain on a four point scale (the Roles and Maudsley scale) and to evaluate their general quality of life using a questionnaire called the SF-36 score.

Subjects returned for follow-up at three time periods: 1 week, 6 weeks and 12 weeks following their third treatment. In addition, patients were asked to return for follow-up evaluation 6 months and 12 months after treatment. At each follow-up visit, the subjects were evaluated by a doctor that did not know what treatment (active or sham) they had received. The results at the 12 week evaluation were used to assess the effectiveness of the treatment.

Subjects were considered to be a success in the study if they had greater than 60% improvement in their heel pain (as measured using the VAS three months after treatment) on at least two of the following three tests: heel pain when taking the first steps of the day, heel pain during daily activities, and heel pain upon application of external pressure.

A summary of the effectiveness results at 3 month following treatment with the Swiss DolorClast® is given in Table 1.

The results of the study (Intent to Treat Group) demonstrated that the active treatment group had a significantly better outcome than the sham treatment group as 61% of the active treated subjects met the definition of success as compared to 42% of the sham subjects. When considering only subjects who completed all three treatments and all follow-up visits (Per Protocol Group), as shown in Table 1, the results in the active group improved as 65% met the definition of success in the study. Results at the 6 month and 12 month follow-up were similar to, or better than, the results at the 12 week evaluation.

The other measures of effectiveness also demonstrated that the active treated subjects had better outcomes in the study as compared to the sham treated subjects. The results on the Roles and Maudsley Score, SF-36 Quality of Life evaluation, and investigator's judgment of effectiveness were all significantly better for the active treated subjects as compared to the group who received a sham treatment. In addition, the subjects in the active treated group had a

significantly higher level of satisfaction with their therapy outcome and were significantly more likely to recommend the EMS Swiss DolorClast® therapy to a friend.

Table 1: Summary of Effectiveness Results 3 Months after Treatment with the Swiss DolorClast®

MEASUREMENT	Active (Dolorclast) Treated at 3 month	Sham Treated at 3 month
Overall success rate, Patients with more than 60% heel pain improvement on 2 of 3 VAS tests (mean value)	64.5%	43.4%
Roles and Maudsley Score		
Excellent or Good	58.40%	41.52%
Fair or Poor	41.60%	58.48%
SF-36 Physical (quality of life assessment) Percent Change from Baseline (average value); negative value indicates improvement	-37.2 %	-19.5%
SF-36 Mental (quality of life assessment) Percent Change from Baseline (average value); negative value indicates improvement	-14.6 %	+8.4%
Investigator Judgment of Effectiveness		
Very good or Good	70.80%	40.91%
Moderate	10.62%	20.91%
Unsatisfactory or Poor	18.58%	38.18%
Patient Judgment of Therapy Satisfaction		
Very or Moderately Satisfied	63.16%	46.36%
Slightly Satisfied or Neutral	18.42%	10.00%
Dissatisfied	18.42% (21/114)	43.64% (48/110)
Patient Recommendation of Therapy to a Friend		
Positive (yes)	91.23%	69.09%
Negative (no)	8.77%	30.91%

No study subjects experienced any unexpected or serious device-related adverse events during the course of the study. The most common event was pain or discomfort during treatment, reported by 30 out of 129 subjects (23.26%) in the active treatment group. Twenty out of 129 reported pain during only one of the treatments, seven of 129 subjects during two of the treatments and only three out of 129 subjects during all three treatments. Three out of 129 subjects reported pain during and after treatment. Eighteen of the reports rated pain during treatment as severe, 22 reports pain rating as moderate, and three reports rated pain as mild. Only one subject requested local anesthesia because of pain during treatment. All other subjects who complained of pain during treatment complete the treatments without local anesthesia. One active treated subject reported mild swelling and pain following treatment and one reported skin reddening that faded following treatment.

11. WHO SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT TREATMENT WITH THE EMS SWISS DOLORCLAST®?

You should contact your doctor to ask any questions about your painful heel syndrome and how treatment with the EMS Swiss Dolorclast® may be helpful.