

Physician Labeling

(“Clinical Application of the Duolith[®] SD1” will be added to Operating Manuals upon PMA Approval.)

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

Manufacturer

STORZ MEDICAL AG
Lohstampfstrasse 8
Tägerwilen, Switzerland CH-8274

US Distributor

CuraMedix
40 Albion Rd.
Lincoln, RI 02865

Release Date: To be determined.

Clinical Application of the Duolith® SD1

Indications

The Storz Duolith® SD1 is indicated for extracorporeal shock wave treatment of heel pain due to chronic proximal plantar fasciitis for patients of age greater than 18 years with a history of failed alternative conservative therapies for at least six months. Chronic proximal plantar fasciitis is defined as traction degeneration of the plantar fascial band at the origin on the medial calcaneal tuberosity that has persisted for six months or more.

Contraindication

- 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
- Patient has a coagulation disorder or taking anti-coagulant medications
- Patient has a prosthetic device in the area to be treated
- Over ischemic tissue in individuals with vascular disease

Warnings

Treatment using the Duolith® SD1 should be performed by a physician or licensed medical professional under the direct supervision of a physician who is trained and experienced in the care of patients with foot and ankle and/or lower extremity disorders and who has completed a training course on the use of the Duolith® SD1 for treatment of heel pain due to chronic proximal plantar fasciitis.

Patients may experience pain/discomfort during and after treatment. To minimize the potential for pain, the working pressure should be slowly increased to a level of 0.25 mJ/mm² during the first 500 impulses. Treatment with analgesics may be appropriate.

Careful positioning of the patient is required to avoid damage to vascular and nerve structures in the treatment area if inadvertently treated with shockwaves.

The Duolith® SD1 may be sensitive to excessive electromagnetic emissions which could result in device malfunction. Do not perform procedures in close proximity to electrosurgery, diathermy or magnetic resonance imaging equipment.

Precautions

The safety and effectiveness of the Duolith[®] SD1 has not been demonstrated in patients with the following conditions/observations:

1. Children less than 18 years of age
2. Inflammation of the lower and upper ankle
3. History of rheumatic diseases, and/or collagenosis and/or metabolic disorders
4. History of hyperthyroidism
5. Paget disease or calcaneal fat pad atrophy
6. Osteomyelitis (acute, sub acute, chronic)
7. Fracture of the Calcaneus
8. Immunosuppressive therapy
9. Long-term (≥ 6 months duration) treatment with any corticosteroid
10. Insulin-dependent diabetes mellitus, severe cardiac or respiratory disease
11. Coagulation disturbance and/or therapy with anticoagulants or antiplatelet agents that may prolong bleeding time
12. Bilateral painful heel, if both feet need medical treatment
13. Previous surgery of the painful heel syndrome
14. Previous unsuccessful treatment of the painful heel with a similar shockwave device
15. History of allergy or hypersensitivity to bupivacaine or local anesthetic sprays
16. Significant abnormalities in hepatic function
17. Poor physical condition
18. Pregnant female
19. History or documented evidence of peripheral neuropathy such as nerve entrapment, tarsal tunnel syndrome, etc.
20. History or documented evidence of systemic inflammatory disease such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, aseptic bone necrosis, Reiter's syndrome, etc.
21. Implanted pacemakers, insulin pumps, defibrillators and/or neurostimulators
22. Open wounds or skin rashes
23. Tendon rupture, neurological or vascular insufficiencies of the painful heel, as assessed using the Semmes-Weinstein Monofilament test and the Ankle Brachial Index

Study Design

The study was a multicenter, randomized, placebo-controlled, prospective, double-blind clinical study enrolling 250 patients (in 1:1 allocation to active treatment with the Duolith[®] SD1 or sham treatment with a device identical to the active device but in which the transmission of the shockwaves to the patient was blocked). The study was conducted to assess the safety and effectiveness of the Storz Duolith[®] SD1 when used to treat unsuccessful conservatively treated patients suffering from painful heel syndrome. For the purpose of this study, painful heel syndrome was defined as chronic proximal plantar fasciitis that had persisted for at least 6 months before study enrollment. The patient and the clinician performing the efficacy assessments were blinded; the clinician administering the treatment (active and placebo) was not. All study procedures for both groups were identical except that of the stand-off used. Active or sham procedures were administered at three (3) treatment visits approximately 1 week apart, with subsequent follow-up visits at 6 weeks, 3 months (Visit 6), 6 months, and 12 months (Visit 8) after the last treatment session. The primary endpoint of comparison between the Duolith Group and Placebo Group is 3 months after the last treatment session (approximately 14 weeks after randomization). Patients considered to be “responders” at the three (3) month follow up, continued to be followed at 6 and 12 months after the last treatment session. A responder is a patient whose heel pain percentage decrease is larger than 60% from baseline at Visit 6 (3 month follow up) for at least two (2) of the three (3) heel pain (VAS) measurements.

The study was conducted at six (6) clinical sites, all in the United States, with two (2) of the six (6) geographic sites for a single investigator. Therefore, results are based on a five (5) clinical sites.

Adverse Events

A total of 101 adverse events in 250 patients were reported during the main IDE approved clinical study (enrollment through 3-Month follow up (Visit 6)). Adverse events reported for the Duolith[®] SD1 consist primarily of pain or discomfort during and after treatment. Events are summarized by treatment group and event category in the table below.

Summary of Number and Percent (%) of Adverse Events by Category and Treatment Group – Safety Population

Category		Duolith Group (n=126)		Placebo Group (n=124)		Total (n=250)	
		Number of Events	%	Number of Events	%	Number of Events	%
1	Pain and/or Discomfort During Treatment	39	50.7	3	12.5	42	41.6
6	Swelling	5	6.5	0	0.0	5	5.0
7	Pain After Treatment	21	27.3	8	33.3	29	28.7
8	Other	12	15.6	13	54.2	25	24.8
Total		77		24		101	

In the Duolith Group, a total of 77 events were reported for 43/126 patients (76.2% of 101 adverse events; 34.1% of 126 patients). In the Placebo Group, a total of 24 events were reported for 17/124 patients (23.8% of 101 adverse events; 13.7% of 124 patients). Pain and/or discomfort occurring during or after treatment represent 60 events in the Duolith Group (60 of 77 events; 77.9%) and 11 events in the Placebo Group (11 of 24 events; 45.8%). Swelling was observed only in the Duolith Group (5 of 77 events; 6.5%). These differences are logical since patients in the Duolith Group received active shockwave therapy.

As shown in the table above, a total of 25 events were categorized as “other” (Duolith Group: 12 events; Placebo Group: 13 events). These events, their rated intensity, relationship, and seriousness are listed by treatment group in the table below. Of these 25 events, none in the Duolith Group were rated as related to treatment. In the Placebo Group, however, two (2) events were rated as possibly related and for two (2) events the relationship was rated as doubtful.

Listing of Adverse Events by Treatment Group

EVENT DESCRIPTION	INTENSITY	RELATION	SERIOUS
<i>Duolith Group</i>			
BONE FRACTURE SPONTANEOUS	Severe	Not Related	No
FALSE SENSATION	Moderate	Not Related	No
INFLICTED INJURY	Mild	Not Related	No
INFLICTED INJURY	Moderate	Not Related	No
INFLICTED INJURY	Moderate	Not Related	No
INFLICTED INJURY	Severe	Not Related	No
INFLUENZA-LIKE SYMPTOMS	Mild	Not Related	No
NEUROPATHY PERIPHERAL	Mild	Not Related	No
PNEUMONIA	Severe	Not Related	Yes
PYELONEPHRITIS	Severe	Not Related	Yes
SINUSITIS	Mild	Not Related	No
SINUSITIS	Mild	Not Related	No

EVENT DESCRIPTION	INTENSITY	RELATION	SERIOUS
<i>Placebo Group</i>			
BONE FRACTURE SPONTANEOUS	Moderate	Not Related	No
BRONCHITIS	Mild	Not Related	No
INFLICTED INJURY	Moderate	Not Related	No
INFLICTED INJURY	Severe	Not Related	No
JOINT PAIN	Severe	Not Related	No
PAINFUL HEEL	Moderate	Possible	No
PAINFUL HEEL	Severe	Not Related	No
TENDON DISORDER	Moderate	Possible	No
TENDON DISORDER	Moderate	Doubtful	No
TENDON DISORDER	Moderate	Doubtful	No
TENDON DISORDER	Moderate	Not Related	No
TOOTH ACHE	Moderate	Not Related	No
UPPER RESP TRACT INFECTION	Moderate	Not Related	No

For adverse events there were 12 events in the Duolith Group (12 of 77; 15.6%) and 13 events in the Placebo Group (13 of 24 events; 54.2%).

Six (6) adverse events were reported for four (4) patients during the long term follow up period of 12 months. No event was serious but one patient discontinued during study participation during long term follow up (12 months) due to ankle pain*. These events are summarized in the Table below.

Adverse Events During Long Term Follow Up (by Treatment Group)

GROUP	REPORTED TERM	INTENSITY	RELATION	SERIOUS
Duolith	Sinus infection, took antibiotics	Moderate	Not Related	No
	Reaction to antibiotics – allergy	Moderate	Not Related	No
	Respiration system infect with Asthma	Moderate	Not Related	No
Placebo	Fracture of 5 metatarsals while vacation	Moderate	Not Related	No
	Patient believes he developed ankle pain*	Mild	Doubtful	No
	Feels ankle hurts from repositioning**	Moderate	Probable	No

*Either non-related, or due to repositioning of ankle during sham treatment

**Repositioning of ankle during sham treatment

Clinical Study

The clinical study used to support approval of the Duolith[®] SD1 for marketing in the United States was a multicenter, randomized, placebo-controlled, prospective, double-blind clinical study enrolling 250 patients (in 1:1 allocation to active treatment with the Duolith[®] SD1 or sham treatment). The study was conducted to assess the safety and effectiveness of the Storz Duolith[®] SD1 when used to treat unsuccessful conservatively treated patients suffering from painful heel syndrome. For the purpose of this study,

painful heel syndrome was defined as chronic proximal plantar fasciitis, or chronic heel spur pain that had persisted for at least 6 months before study enrollment. The patient and the clinician performing the efficacy assessments were blinded; the clinician administering the treatment (active and placebo) was not. All study procedures for both groups were identical except that of the stand-off used. Active or sham procedures were administered at three (3) treatment visits approximately 1 week apart, with subsequent follow up visits at 6 weeks, 3 months (Visit 6), 6 months, and 12 months (Visit 8) after the last treatment session. The primary endpoint of comparison between the Duolith Group and Placebo Group is 3 months after the last treatment session (approximately 14 weeks after randomization). Patients considered to be “responders” at the three (3) month follow up are being followed at 6 and 12 months after the last treatment session (A responder is a patient whose heel pain percentage decrease of heel pain larger is than 60% from baseline at Visit 6 for at least two (2) of the three (3) heel pain (VAS) measurements).

After a screening visit to determine eligibility, the study started at the second visit with the first treatment (after randomization). However, study procedures assigned to the first two (2) visits could be performed at a single visit. Patients were required to meet the following inclusion criteria in order to be enrolled into the study:

1. Age greater than 18 years
2. Ability of patient 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. Chronic proximal plantar fasciitis is defined as heel pain in the area of the insertion of the plantar fascia on the medial calcaneal tuberosity
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 within the past year). The following conservative treatments could 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 analgesic and/or anti-inflammatory gels
 - Therapy with prescription analgesics and/or NSAIDs
 - Local anesthetic injections
 - Local corticosteroid injections
6. Time gap of at least:
 - 6 weeks since the last corticosteroid injection
 - 4 weeks since the last anesthetic injection; iontophoresis, ultrasound and electromyostimulation
 - 1 week since the last NSAIDs
 - 2 days since the last prescription or non-prescription analgesics, heat, ice, massage, stretching, night splinting and orthosis
 7. Scores of ≥ 5 on the three (3) VAS pain scales
 8. Score of 3 (fair) or 4 (poor) on the Roles and Maudsley Scale
 9. Willingness to refrain from the following painful heel related, concomitant therapy: iontophoresis; electromyostimulation; ultrasound; NSAIDs; steroid injections or surgery until Visit 6 (3 months) of this study (shoe modifications and rescue pain medication are allowed during the entire study)
 10. Willingness to keep a Subject Heel Pain Medication and Other Heel Pain Therapy Diary until 12 months after the last treatment
 11. Females of childbearing potential may be entered if they provide a negative urine pregnancy test immediately before the first ESWT treatment
 12. Willingness of females of childbearing potential to use contraceptive measures for 2 months after enrollment into the study

Patients were excluded from study participation for any of the following conditions/observations:

1. Inflammation of the lower and upper ankle
2. History of rheumatic diseases, and/or collagenosis and/or metabolic disorders
3. Patients with a history of hyperthyroidism
4. Active malignant disease with or without metastases
5. Patients suffering from Paget disease or calcaneal fat pad atrophy
6. Patients suffering from Osteomyelitis (acute, sub acute, chronic)
7. Patients suffering from fracture of the Calcaneus
8. Patients with an immunosuppressive therapy
9. Patients with a long-term (≥ 6 months duration) treatment with any corticosteroid
10. Patients suffering from insulin-dependent diabetes mellitus, severe cardiac or respiratory disease
11. Patients suffering from coagulation disturbance and/or therapy with Phenprocoumon, Acetylsalicylic acid or Warfarin

12. Bilateral painful heel, if both feet need medical treatment
13. Patients 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 extracorporeal shockwave therapy will no longer be necessary (e.g., surgery)
14. Time gap of less than:
 - 6 weeks since the last corticosteroid injection
 - 4 weeks since the last anesthetic injection; iontophoresis, ultrasound and electromyostimulation
 - 1 week since the last NSAIDs
 - 2 days since the last prescription or non-prescription analgesics, heat, ice, massage, stretching, night splinting and orthosis
15. Previous surgery of the painful heel syndrome
16. Previous unsuccessful treatment of the painful heel with a similar shockwave device
17. History of allergy or hypersensitivity to bupivacaine or local anesthetic sprays
18. Patients with significant abnormalities in hepatic function
19. Patients in a poor physical condition
20. Pregnant female
21. Active infection or history of chronic infection in the treatment area
22. History or documented evidence of peripheral neuropathy such as nerve entrapment, tarsal tunnel syndrome, etc.
23. History or documented evidence of systemic inflammatory disease such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, aseptic bone necrosis, Reiter's syndrome, etc.
24. History or documented evidence of worker's compensation or litigation
25. Participation in an investigational device study within 30 days prior to selection, or current inclusion in any other clinical study or research project
26. Patients 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
27. Patients with implanted pacemakers, insulin pumps, defibrillators and/or neurostimulators
28. Patients with prosthetic devices implanted in the area of treatment
29. Patients with open wounds or skin rashes
30. Patients suffering from tendon rupture, neurological or vascular insufficiencies of the painful heel, as assessed using the Semmes-Weinstein Monofilament test and the Ankle Brachial Index

Patients who consented to enrollment were randomized but were blinded to treatment assignment. The treatment was repeated three (3) times approximately one week (\pm 4 days) apart. The study procedures, except for the treatment devices, were the same for all patients. Safety and effectiveness data were analyzed through Visit 6 (3 month follow

up). In general, therapy was performed without local anesthesia. Due to a possible pain sensation caused by the shockwave treatment, the applied energy was increased smoothly from lowest energy level 0.01 mJ/mm² up to a level of 0.25 mJ/mm² within the first 500 impulses. After these 500 introductory impulses, 2000 treatment impulses were performed with the regular working application level of 0.25 mJ/mm². Only one (1) patient in the Duolith Group required local anesthesia at Visit 2 (first treatment visit).

The determination of effectiveness was based on two (2) criteria: a composite score for pain (using a 10 cm visual analog scale) and Roles and Maudsley scores when measured at the 3-month follow up visit (Visit 6). The composite score is the sum of three (3) pain (VAS) measurements for the following:

- Heel pain when taking the first steps of the day
- Heel pain while doing daily activities
- Heel pain after application of a standardized pressure device (F-meter)

Heel pain after application of a standardized pressure device (F-Meter) was based on the patient-specific force level at Visit 2 (first treatment visit). Using this same pressure at subsequent visits, the pain level was assessed using the same anchored VAS pain scales.

The second primary criterion for effectiveness was the four-point Roles and Maudsley-Score (JBJS (Br) 1972; Aug 54 3; 499-508) as follows:

- 1 Excellent (No pain, full movement, full activity)
- 2 Good (Occasional discomfort, full movement and full activity)
- 3 Fair (Some discomfort after prolonged activity)
- 4 Poor (Pain limiting activities)

There were eight (8) secondary criteria for effectiveness criteria as follows: Physician's Global Judgment of Effectiveness, Patient Satisfaction with the Outcome of the Treatment, Patient willingness to recommend treatment as judged by patient, Patient's analgesic medication consumption for painful heel, Heel pain overall success defined as percentage decrease of heel pain larger than 60% from baseline at Visit 6 (3 month follow up) for at least two (2) of the three (3) heel pain (VAS) measurement, Heel pain single success when taking the first steps of the day, Heel pain single success while doing daily activities, and Heel pain single success after application of a standardized pressure device. The study results for effectiveness were based on the intent-to-treat population consisting of all patients who received at least one treatment and who had at least one

evaluation visit. Missing values were handled using the Last Observation Carried Forward (LOCF) technique.

Safety endpoints were adverse events (type, intensity, severity, relationship to treatment, etc.) and the clinician’s rating of treatment tolerability. The safety population consisted of all patients receiving at least one treatment.

Patients who were defined as having sufficient response to treatment were followed for an additional six (6) months. Criteria for participation in long term follow up were as follows:

- Percentage decrease of heel pain greater than 60% from baseline to Visit 6 (3 month follow up) for at least two (2) of the three (3) heel pain (VAS) measurements or
- Fulfill three (3) conditions at Visit 6 (3 month follow up): (1) Able to return to work, (2) satisfied with the treatment outcome, and (3) required no concomitant therapy to control heel pain

In addition, all patients with at least one visit at six (6) and 12 months were included in the long term follow up analysis. There were no exclusion criteria.

Summary of Clinical Study Results

Patients were randomized immediately before treatment, with 126 patients assigned to the Duolith Group and 124 patients assigned to the Placebo Group. A total of 17 patients discontinued the study prematurely before Visit 6 (3 month follow up) (Duolith Group: 7 patients, Placebo Group: 10 patients). Reasons for premature discontinuation are summarized by treatment group below.

Reasons for Premature Discontinuation of Patients in the Safety Population (by Treatment Group)

Reason for Premature Discontinuation	Duolith Group (N=126)	Placebo Group (N=124)	Total (N=250)
Worsening of condition	2 (1.6%)	4 (3.2%)	6 (2.4%)
Adverse Event	2 (1.6%)	1 (0.8%)	3 (1.2%)
Worsening of condition and Adverse Event	1 (0.8%)	2 (1.6%)	3 (1.2%)
Administrative Reason	0	2 (1.6%)	2 (0.8%)
Lost to follow-up	2 (1.6%)	1 (0.8%)	3 (1.2%)
Total	7 (5.6%)	10 (8.1%)	17 (6.8%)

Results for the primary effectiveness criteria are statistically significant ($P < 0.025$ one-sided). All sensitivity analyses agreed with confirmatory results and showed statistical significant results. The same trend was demonstrated across study centers. A tabular summary of changes in the median VAS composite score of heel pain and changes in the Roles and Maudsley Score is provided below.

The intent-to-treat (ITT) population consisted of all subjects who received at least one treatment and who had at least one evaluation visit. Missing values were handled using the Last Observation Carried Forward (LOCF) technique.

Summary Comparison of Baseline and Visit 6 (3 Month Follow Up) Composite VAS for Pain with Score Correction* by Treatment Group – ITT Population (LOCF)

COMPOSITE VAS	DUOLITH GROUP (N=125)			PLACEBO GROUP (N=121)		
	Baseline	Visit 6	Change (%)	Baseline	Visit 6	Change (%)
Mean	8.38	3.80	-54.53	8.38	5.01	-40.31
Median	8.30	2.70	-69.20	8.30	5.30	-34.50
SD	0.996	3.247	38.495	1.016	3.400	39.968
Min	5.30	0.00	-100.00	5.30	0.00	-100.00
Max	10.00	10.00	43.80	10.00	10.00	37.50

**Score correction for interfering analgesic therapy as defined in the statistical analysis plan*

Using the Wilcoxon-Mann-Whitney, one-sided test for superiority, the results of the Duolith Group were determined to be superior to the Placebo Group ($P = 0.0027$ one-sided, $MW = 0.6026$, $LB-CI = 0.5306$).

The mean Roles and Maudsley score was reduced from 3.6 to 2.5 in the Duolith Group and from 3.7 to 2.9 in the Placebo Group, with a final group difference for Roles and Maudsley scores of 0.4 in favor of the Duolith Group.

Comparison of Baseline and Visit 6 (3 Month Follow Up) Roles and Maudsley Scores with Score Correction* by Treatment Group – ITT Population (LOCF)

COMPOSITE VAS	DUOLITH GROUP (N=125)			PLACEBO GROUP (N=121)		
	Baseline	Visit 6	Change	Baseline	Visit 6	Change
Mean	3.6	2.5	-1.1	3.7	2.9	-0.8
Median	4.0	2.0	-1.0	4.0	3.0	-1.0
SD	0.49	0.94	1.02	0.48	0.97	0.92
Min	3.0	1.0	-3.0	3.0	1.0	-3.0
Max	4.0	4.0	1.0	4.0	4.0	1.0

**Score correction for interfering analgesic therapy as defined in the statistical analysis plan*

Using the Wilcoxon-Mann-Whitney, one-sided test for superiority, the results for the Duolith Group were determined to be superior to the Placebo Group (P = 0.0006 one-sided, MW = 0.6135, LB-CI = 0.5466).

A tabular summary of the results for secondary effectiveness criteria are summarized below.

Summary of Secondary Effectiveness Results by Treatment Group

SECONDARY EFFECTIVENESS CRITERION	RATING/RESULT	DUOLITH GROUP NUMBER OF PATIENTS (% OF PATIENTS)	PLACEBO GROUP NUMBER OF PATIENTS (% OF PATIENTS)
Investigator's Global Judgment of Effectiveness at Visit 6	Very good	46 (38.66%)	41 (35.96%)
	Good	42 (35.29%)	21 (18.42%)
	Moderate	11 (9.24%)	11 (9.65%)
	Unsatisfactory	11 (9.24%)	16 (14.04%)
	Poor	9 (7.56%)	25 (21.93%)
Patient's global judgment of therapy satisfaction	Very unsatisfied	9 (7.56%)	18 (15.79%)
	Moderately unsatisfied	13 (10.92%)	20 (17.54%)
	Less satisfied	6 (5.04%)	9 (7.89%)
	Neutral	15 (12.61%)	18 (15.79%)
	In general satisfied	19 (15.97%)	11 (9.65%)
	Satisfied	29 (24.37%)	17 (14.91%)
Patient's recommendation of therapy to a friend	Very satisfied	28 (23.53%)	21 (18.42%)
	Yes	95 (79.83%)	68 (59.65%)
Heel Pain Overall Success (larger than 60% from baseline at Visit 6 (3 month) for at least two (2) of the three (3) heel pain (VAS) measurements)	No	24 (20.17%)	46 (40.35%)
	Success	68 (54.40%)	45 (37.19%)
Heel pain single success when taking first steps of the day (percentage decrease of heel pain (VAS) measurements larger than 60% from baseline at Visit 6 (3 month follow up))	Failure	57 (45.60%)	76 (62.81%)
	Success	63 (50.40%)	44 (36.36%)
Heel pain single success while doing daily activities (percentage decrease of heel pain (VAS) measurements larger than 60% from baseline at Visit 6 (3 month follow up))	Failure	62 (49.60%)	77 (63.64%)
	Success	62 (49.60%)	47 (38.84%)
Heel pain single success after application of a standardized pressure device (F-meter) (percentage decrease of heel pain (VAS) measurements larger than 60% from baseline at Visit 6 (3 month follow up))	Failure	63 (50.40%)	74 (61.16%)
	Success	67 (53.60%)	51 (42.15%)
Frequency count of patients with <u>at least one</u> concomitant analgesic therapy during the study	Failure	58 (46.40%)	70 (57.85%)
	No	32 (25.60%)	35 (28.93%)
	Yes	93 (74.40%)	86 (71.07%)

The clinician's judgment of treatment tolerability (a safety endpoint) was rated as "very good" or "good" in 89.1% (106/119) of the patients in the Duolith Group and in 91.2% (104/114) patients in the Placebo Group at Visit 6. However, 74.4 % (n=93 patients) of the Duolith Group and 71.1% (n=86patients) in the Placebo Group required one or more concomitant analgesic medications during the study. The difference between the two (2) treatment groups for tolerability was only 2.1 percentage points in favor of the Placebo Group. (P = 0.1434, two-sided Wilcoxon-Mann-Whitney test, MW = 0.4522, LB-CI = 0.3888).

The results of the multi-center, randomized, placebo-controlled, double-blind clinical study demonstrate that treatment of heel pain due to chronic proximal plantar fasciitis with the Storz Duolith[®] SD1 provides relief for up to 12 weeks duration in a significant proportion of the patient population who have previously failed conservative treatment for a period of at least 6 months. The most likely side effect is pain during/after treatment which was reported by 50.7% of patients in the Duolith Group and 41.6% of patients in the Placebo Group. On average, patients in the Duolith group had more pain relief (pain scores decreased about 55%) compared to patients in the placebo group (pain scores decreased about 40%) between the first visit and the 3 month follow up visit. For this study 74.4% of the Duolith Group and 71.1% of the Placebo Group required one (1) or more concomitant analgesic therapy during the study.

Product Complaints

Product complaints should be reported to Storz Medical at one of the following telephone numbers:

Karl Storz Lithotripsy-America, Inc., Service phone No. (800) 965-4846
CuraMedix, Inc. Customer Service phone No. (877) 699-8399