

# Storz Medical AG

## Duolith® SD1

### Patient Information

#### Extracorporeal Shockwave Treatment for Heel Pain Due to Chronic Proximal Plantar Fasciitis



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

**For more information about your treatments, contact:**

**Dr. Name:** \_\_\_\_\_ **Telephone:** \_\_\_\_\_

**Release Date: To be determined.**

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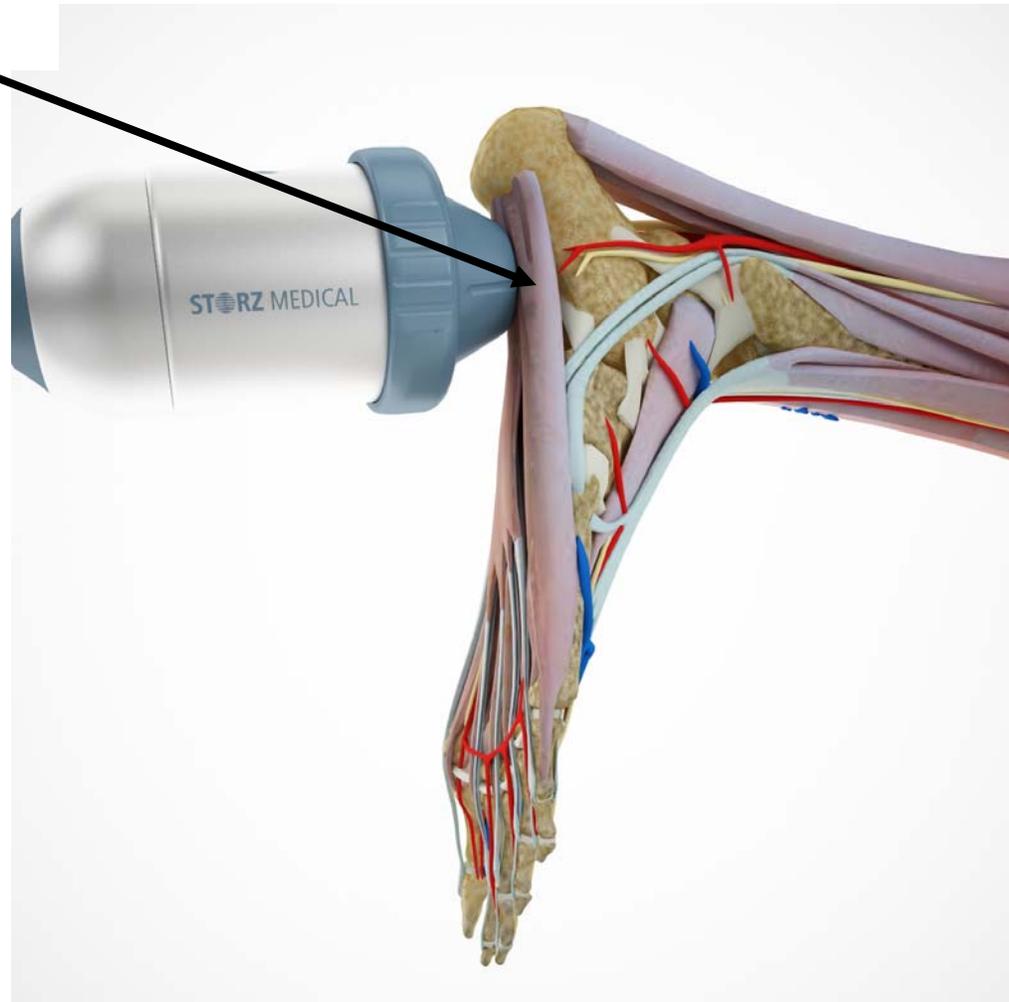
### **What is extracorporeal shockwave therapy?**

“Extracorporeal” means outside the body. Extracorporeal shockwave therapy is the use of shockwaves (usually sound waves) outside the body. This kind of treatment has been used to break up kidney stones from the outside of the body for many years. It is also used to treat heel pain with shockwaves applied to the heel of the foot, but using much lower energy.

### **What is chronic heel pain syndrome?**

“Chronic heel pain syndrome” is the common name of a foot condition with the medical name “chronic plantar fasciitis”. The plantar fascia (shown in the photograph below) is a tissue band that goes from the base of the toes to the heel.

**Plantar fascia**



Plantar fasciitis is a condition that can come and go. When it happens, the band is inflamed and causes pain on the inner side of the heel and sometimes in the arch of the

foot. You can find out more about chronic plantar fasciitis at most reliable medical websites like [www.mayoclinic.com](http://www.mayoclinic.com), [www.heelspurs.com](http://www.heelspurs.com), or [www.aaos.org](http://www.aaos.org).

### **What is the Duolith® SD1?**

The Duolith® SD1 is a medical device for the treatment of heel pain using shockwaves. The Duolith® SD1 has a control unit and a handpiece with a soft cushion at the front end that is used to apply the treatment. The two (2) versions of the Duolith® SD1 are on the front cover. The only difference between the two (2) versions of the Duolith® SD1 is that the T-Top version is designed to sit on top of a counter or on a mobile cart while the Tower version sits on top of its own mobile cart.

### **How is the Duolith® SD1 treatment performed?**

The control unit creates an electrical pulse that is sent down to the handpiece where the shockwave is produced and focused by a reflector. Your doctor will apply the cushioned end of the handpiece to the place on your foot where the pain is the greatest.

Because the amount of pain that patients feel can vary quite a bit, your doctor will start the treatment with low energy and slowly increase the energy for a few shockwaves. Once your doctor and you agree that you can tolerate the shockwaves at the right energy, the actual treatment of 2,000 impulses will be applied. If the shockwaves are too uncomfortable, your doctor can inject your heel with local anesthetic to numb the area. Only one (1) patient in the Duolith Group (0.8% of patients) received an anesthetic and only at the first treatment visit (Visit 2).

The full treatment program is three (3) treatment sessions about one (1) or two (2) weeks apart.

### **Are there any other treatments?**

Treatment of heel pain usually starts with conservative non-surgical and non-invasive treatments that have been reported to improve some patients' symptoms over time. These treatments usually start with pain medications like non-steroidal anti-inflammatory drugs (NSAIDs), rest, and heat. Some other treatments that are available include night splints, orthotics, and physical therapy.

Night splints go from your calf and over the bottom of your foot that you wear while you're sleeping. This splint keeps the foot in the right position, keeping the fascia and tendons in the foot slightly stretched.

Off-the-shelf (over the counter) or individually fitted arch supports can cushion and distribute pressure.

Exercises can be used to stretch the plantar fascia and Achilles tendon. These exercises strengthen lower leg muscles. A therapist can also explain and teach you to use taping to support the bottom of the foot.

If these treatments don't work, steroid injections and surgery are also possible treatments.

***Steroid injections:*** Steroid medication is injected into the area where the plantar fascia attaches to the heel bone. These injections sometimes give temporary relief but having repeated injections can weaken the plantar fascia.

***Surgery:*** Surgery is usually the last treatment option and is typically only performed with the pain cannot be relieved with any other treatments. Like any other treatment, surgery is not always successful and can weaken the arch of the foot.

### **Who could have treatment with the Duolith<sup>®</sup> SD1?**

The Duolith<sup>®</sup> SD1 is a non surgical alternative indicated for the treatment of heel pain due to chronic plantar fasciitis in patients:

- Who are 18 years of age or older
- Who have had symptoms of proximal plantar fasciitis for 6 months or more
- For whom conservative treatments have not relieved heel pain

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.

### **Who should not have treatment with the Duolith<sup>®</sup> SD1 (Contraindications)?**

The Duolith<sup>®</sup> SD1 and other devices like it should not be used in any of 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
- Coagulation disorder or taking anti-coagulant medications
- Prosthetic device in the area to be treated
- Over ischemic tissue in individuals with vascular disease

## **What are the side effects (adverse effects) of treatment with the Duolith® SD1?**

Side effects (adverse events) were reported by patients in both the Duolith Group and the Placebo Group. 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 during or after treatment were reported 60 times in the Duolith Group (60 of 77 events; 77.9%) and 11 times in the Placebo Group (11 of 24 events; 45.8%). Swelling was reported five (5) times in the Duolith Group (5 of 77 events; 6.5%). These differences are logical since patients in the Duolith Group received active shockwave therapy. A variety of other side effects were reported 25 times with 12 reports in the Duolith Group and 13 reports in the Placebo Group. Of these 25 reports, none in the Duolith Group were rated as related to the treatment. In the Placebo Group, however, two (2) events were rated as possibly related (painful heel) and for two (2) events (tendon disorder) the relationship was rated as doubtful.

There were six (6) reports for four (4) patients during the long term follow up period of 12 months. No event was serious but one (1) patient left the study participation during long term follow up (12 months) due to ankle pain.

Other side effects (potential adverse events) reported for other similar devices used for treatment of chronic plantar fasciitis include bruising, collection of blood beneath the skin's surface resulting from internal bleeding (hematoma), temporary or permanent damage to the blood vessels, broken blood vessels visible as red or purple spots on the skin's surface (petechiae), temporary or permanent nerve damage causing decreased sensitivity (hyposthesia) or abnormal skin sensations such as tingling (paresthesia), and rupture of the plantar fascia (tear in the tissue along the bottom of the foot) – a very *rare side effect*.

## **What results can I expect?**

A clinical study of patients with chronic heel pain syndrome who had not gotten relief with conservative treatment was performed. The treatment program was three (3) weekly treatments with the Duolith® SD1 or a device that looked like the Duolith® SD1 but did not transmit the shockwave (Placebo). Patients and their doctors didn't know which device was being used. On average, patients in the Duolith group had more pain relief (pain scores between their first visit and the 3 month follow up visit decreased about 55%) than patients in the Placebo Group (pain scores between their first visit and the 3 month follow up visit decreased about 40%). Also on average, patients in the Duolith group had better functioning (function scores between their first visit and the 3 month

follow up visit decreased about 1.1 points) than patients in the Placebo Group (function scores between their first visit and the 3 month follow up visit decreased about 0.8 points). Even though some patients treated with the Duolith<sup>®</sup> SD1 had good pain relief, some had only a little, and others didn't have any pain relief.

Some patients in both the Duolith Group and the Placebo Group continued to improve after treatments were finished (Duolith Group: 92% (67 of 73 patients); Placebo Group: 84% of patients (43 of 51 patients). At the end of the 3 month follow up, 80% of patients in the Duolith Group said that they would recommend the Duolith<sup>®</sup> SD1 therapy to friends while only 60% of patients in the Placebo Group said they would. At the end of the 12 month follow up, 97% of patients in the Duolith Group said that they would recommend the Duolith<sup>®</sup> SD1 therapy to friends while only 90% of patients in the Placebo Group said they would.

### **Where can I get more information?**

To get more information about treatment with the Duolith<sup>®</sup> SD1, talk to the doctor whose name and phone number are on the cover of this information.

### **User Assistance Information**

#### **Manufacturer**

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