ERCHONIA
World Leaders in Low Level Laser Technology

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About Erchonia

Erchonia is the global leader in low level laser healthcare applications. For nearly two decades, Erchonia has been conducting research & development with the world's leading physicians to advance the science of low level lasers. Erchonia created the low-level laser category after the company was granted the first low level laser FDA clearance for any indication in 2002. Prior to market introduction, all Erchonia lasers are proven to be safe and effective through independent clinical trials. Currently thousands of Erchonia's lasers are used daily to target body fat and create a slimming effect, target onychomycosis, veterinary applications and reduce pain. For additional information, visit www.erchonia.com.

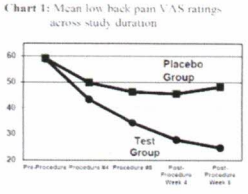
Erchonia's FX 635 Laser FAQ

How does the FX 635 laser work?
The FX 635 laser produces a low-level, or cold, output that has no thermal effect on the body's tissue (you can't even feel it). FDA-approved for both efficacy and safety, FX 635's low level laser technology works by stimulating a physiological response which accelerates healing.

Is the laser FDA approved?
Yes. Erchonia submitted the results of their successful clinical trial and the laser was granted market clearance by the FDA in April 2014 for the reduction of chronic heel pain from plantar fasciitis and a second FDA market clearance in May of 2018 for chronic low back pain of the musculoskeletal origin.

Are there any side effects?
There are no side effects; no pain, discomfort or recovery time of any kind. The FX 635 laser is completely non-invasive.

How was FX 635 tested?
Erchonia received FDA clearance based on a double-blind, randomized, multi-site and placebo-controlled clinical trials.
Plantar Fasciitis - After just two FX 635 treatments on a week for three weeks, patients treated with the FX 635 laser reported reduced pain on the visual analog scale at 2 weeks, 6 months and 12 months post-treatment. On average, patients went from a 68 on the VAS scale down to 8 at the 12-month mark. Those patients who received a placebo laser did a not achieve a statistically-significant reduction in pain at any time during the clinical trial. In order to participate in the study, patients had to have self-reported pain of greater than 50 on VAS of 0 to 100 and be unresponsive to conservative measures.
Chronic Low Back Pain- Erchonia through the pre-IDE process worked with the U.S. FDA on study design and success criteria. The success criteria were defined as a minimum of a 30% decrease in chronic low back pain and 35% of patients in the treated group would experience the minimum pain reduction compared to the placebo group. Clinical trial results showed an average 58% reduction in pain at 8 weeks post treatment.



Can I feel the laser working?
The patient will feel no heat or any sensation from the laser.

How soon could I experience relief?
Results vary from patient to patient but could appear after the first laser treatment.

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FDA Clears Erchonia's New FX 635 Laser for Chronic Heel Pain from Plantar Fasciitis

McKinney, TX – Erchonia today announces the U.S. Food and Drug Administration (FDA) has granted the company 510 (k) clearance to market FX 635, its new low level laser for the relief of chronic heel pain from plantar fasciitis.

Erchonia received FDA clearance based on a double-blind, randomized, multi-site and placebo-controlled clinical trial. In order to participate in the study, patients had to have self-reported pain of greater than 50 on a visual analog scale (VAS) of 0 to 100 and be unresponsive to conservative measures.

After just two FX 635 treatments a week for three weeks, patients treated with the FX 635 laser reported reduced pain on the VAS scale at 2 weeks, 6 months and 12 months post-treatment. On average, patients went from a 68 on the VAS scale down to 8 at the 12-month mark. Those patients who received a placebo laser did a not achieve a statistically-significant reduction in pain at any time during the clinical trial.

Michael Coughlin, MD, the clinical investigator, stated, "Erchonia's FX 635 low level laser for chronic plantar fasciitis demonstrated exceptional results with a marked reduction in almost all of the 30 treated patients. They had suffered from plantar fasciitis for an average of almost a year—one patient had pain for 5 years. All had undergone a variety of non-operative treatments which had all been unsuccessful. At the year follow-up point, almost all patients noted a dramatic reduction in pain and an improvement in function."

Kerry Zang, DPM, added; "I use the Erchonia FX 635 for chronic plantar fasciitis as part of a regenerative medicine protocol. This new technology is a breakthrough for chronic heel pain sufferers, because it offers pain-free treatment with no known side effects or contraindications. Low level laser technology works by stimulating a physiological response which is necessary to healing—whereas other treatments such as cortisone, suppresses inflammation which delays or even stops the healing process."

Charlie Shanks, vice president of Erchonia, comments, "This FDA-clearance for the FX 635 laser is Erchonia's latest example of our ongoing commitment to low level laser technology research. Not only can it provide non-invasive relief to those who suffer from this type of chronic heel pain, the FX 635 laser itself is extremely simple to operate and doesn't require manual operation like all other pain management devices."

The FDA has previously cleared Erchonia's low level lasers for the reduction of chronic neck and shoulder pain; the non-invasive circumference reduction of the arms and the waist, hips and thighs; for liposuction and breast augmentation assistance and the reduction of associated pain; and for the treatment of acne.

For more information, please visit www.erchonia.com.

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FDA Clears Erchonia's New FX 635 Laser for Chronic Low Back Pain

Melbourne, FL - Erchonia Corporation announces another successful clinical trial that has resulted in the granting of an FDA 510(k) market clearance for chronic low back pain of musculoskeletal origin. This grants another first for Erchonia, which started the low-level laser category in January 2002. That year, the FDA issued its first 510(k) market clearance for any low-level laser based on Erchonia's clinical trial for chronic neck and shoulder pain.

This new indication for chronic low back pain is the only laser to be market cleared by the FDA. Erchonia's long history and dedication to the science of low-level laser therapy has led to 22 FDA 510(k) market clearances based on their patented laser systems.

Erchonia through the pre-IDE process worked with the U.S. FDA on study design and success criteria. The success criteria were defined as a minimum of a 30% decrease in chronic low back pain and 35% of patients in the treated group would experience the minimum pain reduction compared to the placebo group. Overall, 72% of patients met the success criteria. Clinical trial results showed an average 58% reduction in pain at 8 weeks post treatment. Steven Shanks, President of Erchonia stated, "We believe we have demonstrated that the use of non-thermal lasers has proven to be a far better option for treating low back pain than that of opioids or NSAIDS."

A recent study published in JAMA in 2018 titled The Space Randomized Clinical Trial looked at chronic low back pain with opioids and NSAIDS over 1 year. Opioids demonstrated a 30% reduction in pain and NSAIDS proved a 34.5% reduction in pain. The publication concluded that "Results do not support initiation of opioid therapy for moderate to severe back pain or hip or knee osteo arthritis pain".

Taking into consideration the minimal effectiveness (30%) and the opioid crisis along with the side effects of NSAIDS for chronic low back pain, doctors and patients may now have safer, more effective option for chronic low back pain of musculoskeletal origin that has been proven successful with no side effects or adverse events.

Erchonia would like to thank doctors Greg Roche, Trevor Berry and Paul Quarneri for their dedication to the science of low-level laser therapy and for helping them document this placebo-controlled, randomized, double-blind, parallel group, multi-center clinical study.

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