

FX 635

Press Kit

Erchonia Corporation

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About Erchonia

Erchonia is the global leader in low level laser healthcare applications. Over the last 15 years, Erchonia has been conducting research and 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 safe and effective through independent clinical trials. Currently thousands of Erchonia’s lasers are used daily to reduce body fat and cellulite, eliminate pain, and treat acne. For additional information, visit [www.erchonia.com](http://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.

**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?**

For both Low Back Pain and Plantar Fasciitis, Erchonia received FDA clearance based on a double-blind, randomized, multi-site and placebo-controlled clinical trial.

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.  Overall, 72% of patients met the success criteria.

**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.



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; non-invasive reduction of cellulite, 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](http://www.erchonia.com).



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. 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](https://jamanetwork.com/journals/jama/article-abstract/2673971) 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](https://www.erchonia.com/laser-applications/), 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.

For more information, please visit <https://www.erchonia.com>.

The History of Erchonia Corporation

Erchonia Corporation is the result of one family’s quest to find a solution to the most basic of problems - how to treat the physical ailments that a family inevitably experiences together.

Frustrated after going from doctor to doctor, Steve and Charlie Shanks watched their father seek relief from chronic pain and arthritis through "low level lasers" that were used at the time in Europe.

Intrigued by the results, the Shanks became dedicated to investigating and researching the burgeoning low level laser field, in particular the possibility of designing and producing a low level laser unit that would be smaller, more efficient and less expensive than the existing European models.

After founding Erchonia in 1996 and embarking on intensive research and development, the Shanks family was able to produce the first prototype of the Erchonia Laser and set up a clinical trial to officially test its efficacy on chronic pain.

In January 2002, after more than three years of clinical research and IRB studies, Erchonia Corporation became the first company in the world to receive FDA market clearance for the Erchonia Laser in the treatment of chronic pain.

Still a family-run business to this day, Erchonia maintains its quality production standards and is involved in almost every facet of its products’ creation: research, development, fabrication of components and assembly of finished goods in-house.

Today, Erchonia is the global leader in low level laser healthcare applications. Over the last 15 years, Erchonia has conducted research & development with the world’s leading physicians to advance the science of low level lasers. 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 reduce body fat, eliminate pain, accelerate healing, and treat acne.

"We find it greatly rewarding that we are developing and manufacturing low level laser products that help people, just as they helped our father," says Charlie Shanks, vice president of Erchonia. "We are committed to the advancement of such technologies and are continuing to research new non-invasive and risk-free applications."



Erchonia FDA Market Clearance

Over the last 18 years of R&D on low level lasers, Erchonia has developed a wide range of non-invasive, drug-free, aesthetic & therapeutic low level laser applications.

Erchonia has received numerous FDA 510(k) market clearances for its low level lasers:

* **January 2002:** for treatment of chronic neck and shoulder pain
* **September 2004:** for liposuction assistance & reduction of associated pain.
* **May 2005:** for treatment of acne
* **April 2008:** for breast augmentation assistance & reduction of associated pain.
* **August 2010:** for circumference reduction of the waist, hips and thighs (Zerona)
* **June 2012:** for the non-invasive reduction of arm circumference (Zerona)
* **August 2013:** for the non-invasive treatment of cellulite on the thighs, buttocks and lower abdomen (Verjú)
* **October 2013:** for the relief of minor chronic neck and shoulder pain; reduce pain after liposuction of the thighs, hips and stomach; or reduce post-surgery pain (XLR8)
* **April 2014:** for the relief of chronic heel pain from plantar fasciitis (FX 635)
* **October 2014**: for Non-Invasive Body Contouring of the Waist, Hips and Upper Abdomen for BMI 30-40
* **January 2015:** for Zerona OTC - Non-Invasive Dermatological Aesthetic Treatment for the reduction of the circumference of the hips, waist and thighs
* **May 2015:** for Zerona-Z6 (6) Week Protocol - Non-Invasive Dermatological Aesthetic Treatment for the Reduction of Circumference of Hips, Waist, Thighs and Upper Abdomen (1 Tx per Week for 6 Weeks)
* **February 2016:** Erchonia EVRL –

a. while using the red diode, for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin,

b. and while using the violet diode, to treat dermatological conditions, and specifically indicated to treat moderate inflammatory Acne Vulgaris.

* **June 2016:** for LunulaLaser. The LunulaLaser device is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.)
* **December 2016**: Zerona Z6. **Non-invasive treatment for reduction of body circumference.**
* **May 2018:** for FX 635. Indicated for use to treat chronic low back pain of the musculoskeletal region



Erchonia R&D

Low level laser technology is emerging as a major medical device platform within healthcare.

* Low level lasers have proven to be a safe and effective option in aesthetics & therapeutic healthcare.
* Low level laser technology is over three decades old and has never produced a single adverse event.
* A large body of clinical studies has been published highlighting the potential for low level lasers to serve as independent or adjunctive healthcare procedure.

Given the growing evidence of complications associated with invasive procedures and commonly prescribed drugs, non-invasive, drug-free alternatives are gaining traction among consumers, healthcare professionals, insurance companies, and government agencies alike. Low level lasers are even efficacious in a wide variety of dental care applications and in veterinary medicine.

To meet this growing demand for laser healthcare solutions, Erchonia Corporation is investing heavily on research and development. Erchonia R&D efforts are already receiving recognition and support from a wide range of opinion-leading healthcare professionals.

Erchonia develops a wide variety of application-specific low lever lasers from the conceptual stage, to pilot studies, through to clinical trials and FDA approval of its final products. Erchonia Corporation prefers to maintain control over manufacturing in order to ensure Q&A standards are met and there are no plans for external contract manufacturing.

Erchonia low level laser applications already in clinical trial or have a clinical trial pending include:

*Autism*

*Asthma*

*Bone Healing & Osteoporosis*

*Capsular Contracture*

*Cellulite Reduction*

*Cholesterol & Triglyceride Reduction*

*Chronic Ulcers Healing with PRP*

*Diabetes*

*Hair Restoration*

*Hypertonic & Hypotonic Solution for Facial Wrinkle Reduction & Body Contouring*

*Metabolic Disorder*

*Onychomycosis (nail fungus)*

*Parkinson’s*

*Foot Pain from Plantar Fasciitis*

*Spinal Cord/Nerve Regeneration*

*Staphylococcus Aureus (MRSA)*

*Stem Cell Proliferation & Enhanced Efficacy*

*Wound / Burn Healing*

It is important to note that many of the above aesthetic & therapeutic applications have already been effectively addressed with Erchonia low level lasers in “pilot studies” (a lead indicator of clinical trial results).