LunulaLaser

Press Kit

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About Erchonia

Erchonia is the global leader in low level laser healthcare applications. For nearly 2 decades, 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, eliminate pain, accelerate healing, treat acne, treat the appearance of cellulite, treat onychomycosis and veterinary applications. For additional information, visit www.erchonia.com.

Erchonia's Lunula Laser FAQ

1. **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 June 2016 for the treatment of onychomycosis.

2. **What are the advantages of the Erchonia Lunula onychomycosis laser device?**
   This device is unique in that it is the only true, dual diode, non-thermal, unattended Class 2 laser that offers multiple benefits. The Lunula combines the anti-fungal effects of the 405 nm wavelength with the regenerative outcomes of a 635 nm wavelength.
   The Lunula produces two wavelengths, 635 nm and 405 nm, both of which have been enriched by a proprietary rotating line-generated laser beam. The Lunula's specially designed delivery mechanism maximizes both photon concentration and treatment surface area.
   The Lunula's patented delivery system ensures that all infected tissue, nail bed and most importantly, the proximal germinal/matrix tissue are properly targeted and treated.

3. **Are all laser wavelengths the same?**
   No. The higher wavelengths have less energy and normally more power is added which produces heat. Normally output power of watts and wavelengths of 900nm or higher are considered Class IV devices and produce an increase in temperature in the tissue being treated.
   The lower wavelength lasers, Class 2, Class 3A and 3B depending on power output, do not rely on heat production. Cold lasers initiate true physiologic responses, photo modulation. The Class2/3A/3B lasers have wavelengths 700 nm or lower.

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

5. **Is the tissue response the same with the lower wavelengths in the Lunula?**
   No, the lower the wavelength, the greater energy produces and the greater anti-microbial/antifungal effect, high powered lasers work by boosting power to overcome the anti-microbial/antifungal but this can cause tissue destruction which is evidenced by the heat and smoke dangerous smoke plumes they produce.

6. **What is the advantage utilizing a multiple diode approach in the treatment of onychomycosis?**
   The 635 nm wavelength stimulates endogenous mechanisms, which enhances the immunological function of resident neutrophil and macrophage function to further degrade the infectious agent. This wavelength also induces tissue rejuvenation, increased vascularization, which enables the dual diode approach to accelerate the growth of new clear nail growth.
   The 405 nm wavelength provides anti-microbial, antibacterial and anti-fungal effects.
   The patented dual diode approach provided by the Lunula Onychomycosis Device provides symbiotic wavelengths that enhance new clear nail growth at 6 months.

7. **What kind of response have been seen when utilizing the dual diode lower wavelength approach in the treatment of onychomycosis?**
   In the clinical trial results 89% of patients respond.

8. **Are there any complications with LunulaLaser therapy?**
   No complications were reported in all 4 LunulaLaser clinical trials.

9. **Is it recommended to obtain fungal cultures prior to low-level laser therapy**?
   During the Lunula clinical trial, a positive mycology study was received on all patients.

10. **What are the risks with using a heat-based Class IV laser as opposed to a true cold laser?**
    When using heat-based lasers to treat nail fungus, there are risks: thermal burning, necrosis, pain, threat of airborne mycosis with the potential of pulmonary ingestion with resultant long-term infection and disease. Both patients and medical staff can be at risk from exposure to laser plumes.
    When utilizing true cold laser therapy, such as the Lunula device, there is virtually no risk, either to the patient or the treating physician. The worst thing that can happen with true cold laser therapy for onychomycosis is nothing.

11. **Is debridement of the toenail necessary when utilizing laser therapy to treat onychomycosis?**
    No. During the Lunula studies, no debridement was performed.

12. **What is the standard treatment protocol?**
    In the clinical trial, treatments consisted of 4 weekly 12 minute treatments.

11. What are the Advantages of Lunula Low Level Laser for the Treatment of Onychomycosis?

- no chance of developing microbial resistance to this form of treatment
- does not interfere nor interact with any systemic medicine
- no chance for liver toxicity
- treatment protocol is painless, ensuring good patient compliance
- no pain during treatment
- no downtime
- unattended treatment

12. **How does the LunulaLaser work?**
    Peroxynitrite is a compound that has potent anti-microbial effects. This compound is formed when Nitric Oxide (NO) reacts with Reactive Oxygen Species (ROS). The Lunula Laser by Erchonia, the only true Low Level Laser used to treat onychomycosis, uniquely has two different laser diodes; a 635nm and a 405nm. This combination of wavelengths is crucial in that the 635nm diode produces NO and the 405nm diode is the best producer of ROS, both within the visible light spectrum. Cell destruction is triggered by the cytotoxic effects of peroxynitrite.
    NO + ROS = peroxynitrite destroys fungal pathogens
    The 635nm laser enhances mitochondrial energy metabolism, which generates NO, and this is combined with the 405nm laser, which generates ROS, produces peroxynitrite. This by-product is cytotoxic and destroys pathogenic bacteria, fungi and protozoa.

13. **Can a patient become re-infected with fungus once there is clearance?**
    Yes, patients can become re-infected if they do not take precautions. If a spouse or significant other has clinical nail fungus, it is advised to not treat them without treating their partner. It is recommended for patients to take other precautions to prevent re-infection. Recommendations include, using a gas sterilizer to treat their shoes, using anti-fungal spray to use after wearing closed toe shoes and spray their showers with Tylex or other cleanser, all with the hope of preventing re-infection.

14. **What kind of clinical results are experienced with the Lunula Laser?**
    Clinical trial results proved and average of 6.1 mm New Clear Nail Growth at 6 Months.

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Lunula Talking Points

For Patients	For Doctor
1. 89% of Patients Respond	1. 89% of Patients Respond
2. 46% of New Clear Nail Growth at 6 Months	2. 6.1 mm New Clear Nail Growth at 6 Months
3. Healthy Nails Can Take (1) Year to Grow Out Completely	3. Positive Mycology Study on All Patients
4. Unattended, No Pain, No Downtime and No Dangerous Smoke Plumes	4. Unattended, No Pain, No Downtime and No Dangerous Smoke Plumes
5. FDA Market Cleared for New Clear Nail Growth at 6 Months.	5. FDA Market Cleared for the Treatment of Onychomycosis
6. Clinical Results in as little as (4) Treatments	6. (3) Independent Physicians Validated Software for New Clear Nail Growth as Suggested by U.S. FDA
7. Patents: US PAT 6,013,096; US PAT 6,746,473; US PAT 8,409,264; US PAT 8,814,924; US PAT 8,097,029; US PAT 7,118,588; US PAT 7,947,067; US PAT 7,922,751 and several U.S. and International Patents Pending.	7. Device and Process Patents: US PAT 6,013,096; US PAT 6,746,473; US PAT 8,409,264; US PAT 8,814,924; US PAT 8,097,029; US PAT 7,118,588; US PAT 7,947,067; US PAT 7,922,751 and several U.S. and International Patents Pending.

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Nail Fungus Sufferers Find Relief in New Laser Treatment
Lunula receives FDA approval, launches next month

MCKINNEY, Texas -- With the summer fun and flip flop season in full swing, those suffering from discolored toenails start to worry about what others think of their feet. Toenail fungus sufferers can now enjoy clear nail beds with the FDA 510(k) approval of the Lunula Laser, an Erchonia Corporation low-level laser.

The Lunula device increases the amount of clear nail in patients infected with onychomycosis, or nail fungus. In the clinical trial, 67 percent of patients met the success criteria of three millimeters of clear nail growth. By six months after the initial treatment, these patients average more than five millimeters of new growth.

This is the first and only low-level laser to receive FDA 510(k) marketing clearance for onychomycosis. "Lunula is the future of treating onychomycosis," said Dr. Kerry Zang, founder of the Arizona Institute of Footcare. "The results seen in the clinical trial are spectacular and we are eager to provide Americans with the opportunity to treat this nail fungus with an effective product."

The portable Lunula device applies a laser to the area infected by onychomycosis. During the study, patients between 18 and 70 years old received treatments once a week for four weeks.

Previously, treatment for nail fungus included prescription oral antifungal medication, which increased potential for liver toxicity issues, or else called for ineffective, over-the-counter topical creams. "Nail fungus is a big problem and the toxicity of the available drugs is almost as bad," said Dr. Robert Sullivan. "Lunula gives doctors a viable treatment option: no blood tests, no pain and no mess." Zang and Sullivan lead the research behind Lunula. Prior to FDA 510(k) approval, the product went through four clinical trials which recorded no known side effects.

The 510(k) is a premarketing submission to the FDA that demonstrates that the device marketed is safe and effective. The premarket approval for the 510(k) is the most rigorous type of device marketing application accepted by the FDA.

Founded in 1996, Erchonia Corporation is the world leader in low-level laser technology. The company created the low-level laser category in 2002 when it received an FDA 510(k) market clearance for low-level lasers. Erchonia was the first company to receive this FDA 510(k) distinction. For more information, visit www.erchonia.com or call 888-242-0571.

For additional information, image and interview requests, contact Marjorie Comer, Axia Public Relations at 888-PR-FIRM-8, ext. 700.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/nail-fungus-sufferers-find-relief-in-new-laser-treatment-300293487.html
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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. For nearly 2 decades, 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."

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Erchonia FDA Market Clearance

In nearly 2 decades 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.)

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).