



Press Kit

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ERCHONIA
World Leaders in Low Level Laser Technology

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 Zerona Laser FAQ

How does the Zerona laser work?

The Zerona 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, the non-invasive Zerona laser helps the body absorb and process fat by stimulating biological function.

Because the laser is a coherent light source, the photons move in a uniform-parallel manner and are not scattered like light from other light sources; therefore depth penetration past the skin is far greater with the laser than from any other light source.

Is the laser FDA approved?

Yes. Erchonia submitted the results of its successful clinical trial and the laser was granted market clearance by the FDA in August 2010 for the non-invasive circumferential reduction of the waist, hips and thighs. Since then, the Zerona has obtained 4 additional FDA 510(k) clearances with the last being for overall body circumference reduction.

What does the Zerona laser do to fat?

As fat congregates in interstitial spaces of cells for a certain amount of time, the Zerona laser stimulates the photo-receptors in each cell. The photo-receptors absorb photons at 635nm, and by exciting these photoreceptors, the Zerona is able to stimulate the excess fat to leave the cell, producing a beneficial clinical effect. It does not destroy the cell or the fat.

When the fat storing cells are exposed to the red laser light, the biological response observed is the formation of a "pore" or an opening in the protective membrane of the cell. By altering the integrity of the cell's membrane, the fatty material is quickly removed from the cell, causing the once plump cell to collapse, but is not destroyed, so it can still secrete beneficial hormones.

In summary, Zerona laser therapy stimulates a photo-acceptor that then alters the unique dynamics of the cell, causing an opening in the membrane to form forcing the fatty material to seep through that opening leaving the cell. Because the cell no longer retains its stored content, it

collapses, the material is absorbed by the lymphatic system, and the end result is the reduction of a subcutaneous fat pocket.

Where does the fat go?

Once the fatty material leaves the cell, it is quickly absorbed by the lymphatic system, where it is transported to the liver for processing. The excess fat is then removed naturally by the body without the negative side effects and downtime associated with more invasive procedures such as liposuction.

Are there any side effects?

There are no side effects; no pain, discomfort or recovery time of any kind. The Zerona laser is completely non-invasive.

How was Zerona tested?

Zerona was tested in multiple double blind, randomized, multi-site and placebo-controlled studies which revealed that in two weeks of trials with the Zerona laser—without surgery, diet restrictions, supplements or any other adjuncts—clients lost an average of 3.72 inches from their waists, hips and thighs. Zerona was also published in multiple peer reviewed journals.

What is the standard Zerona treatment?

The Zerona treatment consists of six treatments (one, forty-minute treatment every other day for two weeks). The laser is directed towards the anterior (front) side for twenty minutes, then the client flips over, and the laser targets the back (posterior) for twenty minutes. The client will feel no heat or any sensation from the laser.

What maximizes results?

Although not required, results may be maximized with lymphatic supplements such as niacin, proper hydration, light exercise, and minimizing alcohol and caffeine.

How soon could I see results?

Results vary from client to client but could appear after the first treatment. Best results typically occur a week after the final (sixth) treatment.

Where can I see before and after images?

For before and after images or more information, please visit www.myzerona.com.



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FDA Clears Erchonia's Zerona Laser for the Non-Invasive Reduction of the Arms

McKinney, TX, June 6, 2012 – Erchonia today announces the U.S. Food and Drug Administration (FDA) has granted 510 (k) clearance to market [Erchonia's Zerona](#) body-contouring laser treatment for the non-invasive reduction of arm circumference based on a level 1 blinded and controlled clinical trial.

"The arms have always been a difficult area to treat through diet, exercise or even surgery," says Steven Shanks, president of Erchonia. "But in just 2 weeks of treatments with the Zerona laser, Erchonia's study proved clients could lose approximately 4 cm off of their arms without diet, exercise or nutritional supplementation. Clients treated with a placebo laser did not show any significant changes in arm reduction."

The upper arms are unique in that no other confounding factors such as diet that can affect the circumference, especially over a relatively short period of time. The results of the study showed a highly statistically significant difference in circumference reduction, which was still present at least 7.6 months after treatment, between the Zerona treated vs the sham treated clients. It also revealed a very high degree of client satisfaction in the Zerona treatment group.

Dr. Mark Nestor, the lead investigator for the study, adds, "After seeing firsthand the results of the Zerona noninvasive body sculpting device on clients' waists, hips and thighs, I wanted to assess the efficacy of the low-level laser on the upper arms in a rigorous level 1, double blind, multicenter, sham-controlled study. The study shows Zerona's low-level laser therapy is effective in reducing upper arm circumference without any pain or side effects."

This is the second FDA 510k market clearance Erchonia has secured for its Zerona technology. In August 2010, Zerona became the first and only device with 510 (k) market clearance for the circumference reduction of the waist, hips and thighs.

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

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New Cold Laser Technology Fights Fat with Light

Studies Prove Zerona Laser Removes Fat and Contours without Pain or Downtime

McKinney, TX – Erchonia, the global leader in low level laser healthcare applications, announces the launch of the new Zerona cold laser. Zerona is a low level laser that removes fat and contours the body without invasive surgery.

Zerona was tested in a double blind, randomized, multi-site and placebo-controlled study, which revealed that in two weeks of trials with the Zerona laser—without surgery, diet restrictions or any other adjuncts—clients lost an average of 3.72 inches from their waists, hips and thighs. Some clients lost as much as twelve inches.

In contrast to high-power, high-heat lasers that are used in various surgical procedures, the new Zerona (which means “to shrink”) laser produces a low-level, or cold, output that has no thermal effect on the body's tissue. Instead, the non-invasive laser helps the body absorb fat by stimulating biological function. As fat congregates in interstitial spaces of cells for a certain amount of time, the Zerona laser stimulates the body to rid itself of that excess fat using the body’s normal processes.

Excess fat is then removed naturally by the body without the negative side effects and downtime associated with more invasive procedures such as liposuction.

“We believe Zerona is the future of body contouring without surgery,” says Charlie Shanks, VP of Erchonia. “There is simply nothing else like it on the market. It offers clients a noninvasive body contouring alternative with fantastic results and without side effects.”

Erchonia lasers have achieved FDA market clearance (510K) for liposuction in 2004, acne in 2005, chronic pain in 2002, and for breast augmentation in April 2008. The Zerona laser received market clearance from the FDA in August 2010.

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

About the protocol in the clinical trial

Placebo clients were treated with a 635nm L.E.D. The test group was treated with the Zerona Laser. All clients were treated six times over two weeks for twenty minutes on each side of the body (forty minutes total). Clients were instructed not to restrict their diets. Clients did not feel pain during the non-invasive treatment, did not receive anesthesia, and assumed normal activities after each treatment.

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Erchonia Receives 7th FDA Market Clearance for Non-Invasive Fat Loss New once a week protocol allows for more treatment flexibility

McKinney, TX- June 2, 2015- Erchonia announces today that they have received their 7th 510(k) market clearance and the 2nd in 2015 from the US FDA for non-invasive fat loss which is measured by circumference reduction. Erchonia has also been published 20 times in journals and text books with our patented laser processes.

Erchonia has been researching fat loss since 1998 and has performed several level 1 blinded and controlled clinical trials on circumference reduction. "We have more 510(k) market clearances on non-invasive fat loss than all other companies combined" stated Steven Shanks President of Erchonia Corp.



The new study was performed on 54 subjects who participated in a once a week treatment for (6) weeks; the results showed that patients continued to see a reduction 2 weeks post treatment which is believed to be due to the process of fat metabolism. What this study demonstrated was that patients with a 25 to 40 BMI should expect to lose 6 inches from their waist, hips, thighs, and upper abdomen. "I would implore consumers seeking such treatments to compare this to other body contouring device's that have FDA market clearance, such as those that freeze fat which can only claim according to their 510(k) statements to *effect appearance of fat* in 2 to 4 months". "After considering all the data potential patients should contemplate if they would like to lose 6 inches of fat in 6 weeks with no known side effects with the *New Zerona Z6* laser protocol or be able to affect the appearance of fat in 2 to 4 months with a risk of pain, and side effects

associated with other devices" says Charlie Shanks, Vice President of Marketing.

We would like to thank Carl Thornfeldt M.D and Paul Thaxton M.D for their dedication to research and helping Erchonia with its latest achievement.

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

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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 over two 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."

Erchonia FDA Market Clearance

Over the last two 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 the appearance of cellulite on the thighs, buttocks and lower abdomen (Verjú Laser System)
- **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 (Allay)
- **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:** for Zerona OTC Overall Body Circumference Reduction. The ZERONA Z6 OTC Laser is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference.
- **May 2018:** for FX 635. Indicated for use to treat chronic low back pain of the musculoskeletal region



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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 level 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.

For updates on Erchonia research, please go to www.clinicaltrials.gov and then search for "Erchonia".