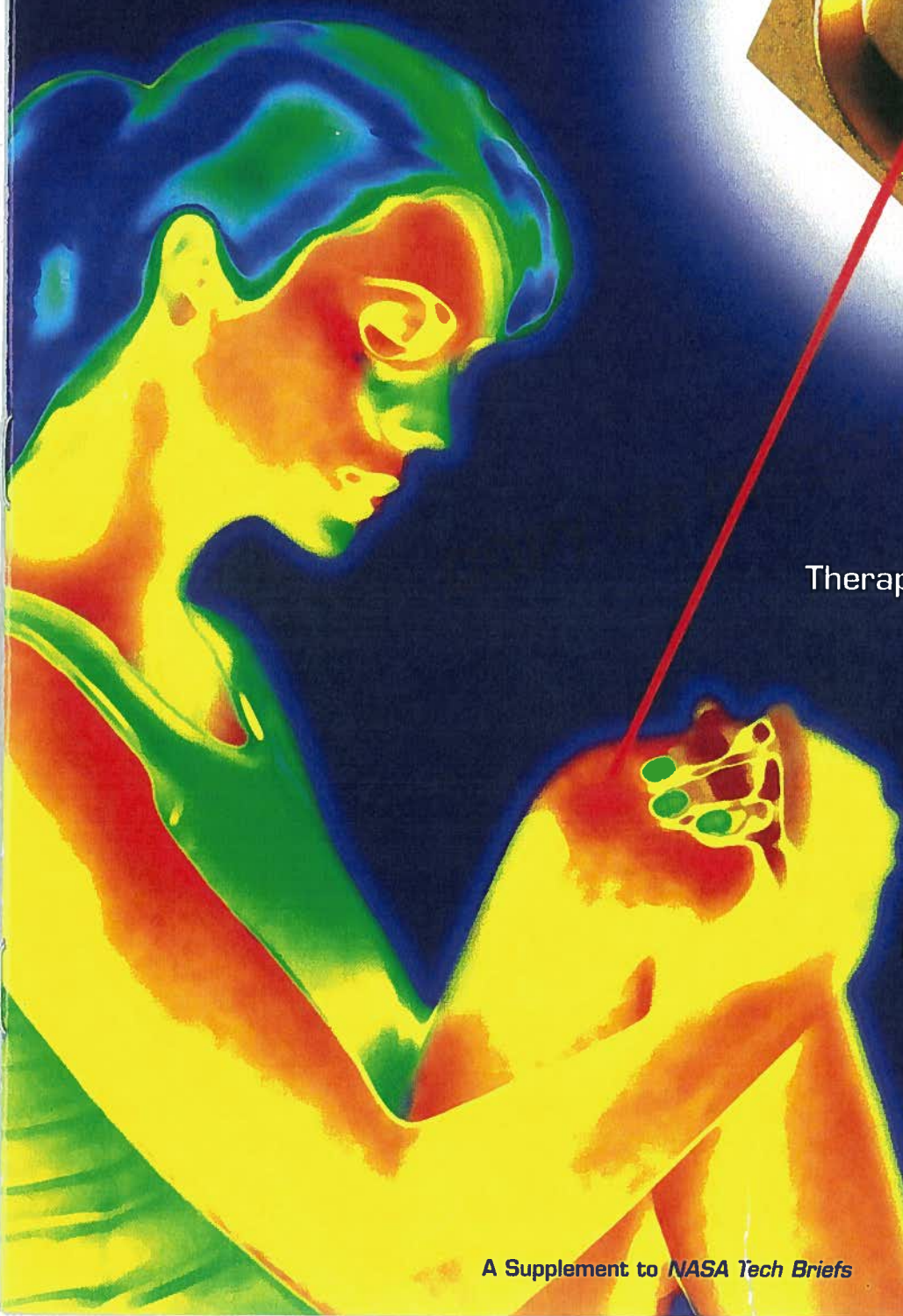


November 2009

MEDICAL DESIGN BRIEFS



ARTICLES

Cold Laser and LED
Therapy Provide Non-Invasive
Treatment Options

Heart Valve Stent
Implants for Children

Magnetic Plungerless
Injection System

Mission Accomplished:
NASA-Developed
Spinoffs

Cold Laser and LED Therapy Provide Non-Invasive Treatment Options

The use of low-level lasers for the therapeutic treatment of disease is growing. Low-level laser therapy (LLLT) covers a number of techniques, including biostimulation, cold laser therapy, and photodynamic therapy. LLLT uses low-level lasers (less than 500 mW) or light-emitting diodes (LEDs) to stimulate or inhibit the cellular energy of tissue without heating it. LLLT helps in wound healing, pain relief, and muscle relaxation. Various LLLT methods used in cosmetic procedures include hair removal and re-growth, cellulite reduction, and reducing scars and inflammatory skin conditions.

Laser biostimulation is used to promote healing in many conditions. Biostimulation treatments use a laser to deliver healing heat to the patient's skin. The procedure is non-invasive, painless, and there are generally no post-treatment restrictions.

In photodynamic therapy, a drug is first administered, and a selected wavelength of laser light is used to trigger a reaction that kills cancerous cells or stops a normally progressive disease.

Photodynamic Therapy

In 1993, Quantum Devices, Inc. (QDI) of Barneveld, WI, began developing the HEALS (High Emissivity Aluminiferous Light-emitting Substrate) technology to provide high-intensity, solid-state LED lighting systems for NASA space shuttle plant growth experiments. The company evolved out of cooperative efforts with the Wisconsin Center for Space Automation and Robotics (WCSAR) at the University of Wisconsin-Madison — a NASA center for the Commercial Development of Space. Ronald W. Ignatius, QDI's president and chairman, was one of WCSAR's industrial partners at the time. WCSAR was conducting research on light sources for promoting food growth within closed environments where humans would be present for a long duration, such as the shuttle and the International Space Station.

Ignatius experimented with LEDs, demonstrating that red LED wavelengths could boost the energy metabolism of cells to advance plant growth and photosynthesis. This finding prompted Ignatius to develop a line of LED products that emit the exact wavelength of light that plants use in photosynthesis.

In 1989, Ignatius formed QDI to bring the salt-grain-sized LEDs to market, and in October 1995, the light sources made their space shuttle flight debut on the second U.S. Microgravity Laboratory Spacelab mission.

When NASA determined that red LEDs could grow plants in space, Marshall Space Flight Center in Alabama awarded QDI Small Business Innovation Research (SBIR) contracts to investigate the effectiveness of the LEDs in medical applications. The contracts focused on increasing energy inside human cells. It was NASA's hope

that the LEDs would not only yield medical benefits on Earth, but also help stem the loss of bone and muscle mass in astronauts. Also, since wounds are slow to heal in a microgravity environment, LED therapy could accelerate healing and keep what would be termed as minor wounds on Earth from becoming catastrophic in space.

In addition to promoting cell growth, the red LEDs can activate light-sensitive, tumor treating drugs that, when injected intravenously, could completely destroy cancer cells while leaving surrounding tissue virtually untouched. The technique, approved by the FDA for use in laboratory and human trials, is known as Photodynamic Therapy (PDT).

QDI set out to alter a surgical probe that could emit long waves of red light to stimulate a benzoporphyrin-derivative drug called Photofrin, which delivers fewer post-operative side effects than



The wound-healing LED array device made by QDI is based on NASA-developed technology for plant growth. A nurse practitioner places the LED array on the outside of a patient's cheek, where it shines for just over a minute each day, promoting wound healing and preventing mouth sores caused by radiation and chemotherapy. (B. Himelhoch, Medical Center Graphics Inc.)

Cold Laser and LED Therapy



The Portable Laser System from Apollo Physical Therapy Products is designed for field use in treating pain, injuries, wounds, fractures, and neurological conditions.

comparable drugs. Ignatius additionally developed a working relationship with Dr. Harry Whelan, a professor of pediatric neurology and director of hyperbaric medicine at the Medical College of Wisconsin in Milwaukee. Whelan had developed a brain cancer surgery technique that uses drugs stimulated by laser light to accelerate healing.

Both doctors, with NASA researchers, successfully altered the probe for pediatric brain tumors and the prevention of oral mucositis — a common side effect of chemotherapy and radiation treatments in pediatric bone marrow transplant patients — at the Medical College of Wisconsin. Many times, young bone marrow transplant recipients contract this condition that produces ulcerations in the mouth and throat, severe pain, and in some cases, inflammation of the entire gastro-intestinal tract. Swelling and bleeding occur, and chewing and swallowing become difficult, if not impossi-

ble — affecting a child's overall health because of reduced drinking and eating.

In May 1998, a 20-year-old female became the first patient to undergo surgery with the modified probe. The young woman had endured six brain surgeries as well as chemotherapy and radiation treatments over a span of 10 years, but her aggressive cancer kept coming back. Having exhausted all of her conventional treatment options, she turned to the NASA-sponsored Photodynamic Therapy technology.

During the procedure, surgeons excised as much of the recurring brain tumor as they could, then injected the light-activated Photofrin into her bloodstream and inserted the LED probe into the remaining tumor tissue. The probe, which casts long wavelengths that generate less heat and penetrate deeper into tissue than the shorter wavelengths of traditional medical lasers, proved to be both safe and effective, as the tumor

never returned and the patient recovered with no complications.

QDI introduced the WARP 10 (Warfighter Accelerated Recovery by Photobiomodulation), a high-intensity, handheld, portable LED unit intended for the temporary relief of minor muscle and joint pain, arthritis, stiffness, and muscle spasms. It also promotes relaxation of muscle tissue and increases local blood circulation. Unlike the surgical probe, the WARP 10 does not require intravenous medicine; instead, the unit can be placed directly on the skin where treatment is to occur.

The WARP 10 was designed to aid armed forces personnel on the front lines with immediate first aid care for minor injuries and pain, thereby improving endurance in combat. The device produces 80 times more photon energy than a 250-Watt heat lamp, yet it remains cool to the touch. The power advantage reduces the time required for each therapeutic dose and provides for faster multi-dose exposures when needed, without the harmful effects of ultraviolet solar radiation. The U.S. Department of Defense and the U.S. Navy are currently issuing WARP 10 to crews on submarines and Special Forces operations.

QDI offers an FDA-approved consumer version with the same power and properties of the military model, as an alternative to the complications associated with overuse of non-steroidal anti-inflammatory drugs (NSAIDs) for persistent pain relief.

Visit <http://info.hotims.com/22930-172> for more information.

Cold Laser Therapy

The term cold laser refers to the use of low-intensity or low levels of laser light. These laser devices are thought to help some types of pain, inflammation, and wound healing, and are used directly on or over the affected area. Cold lasers are also used for acupuncture, using laser beams rather than needles to stimulate the body's acupoints.

Scientific studies are underway using low-level laser devices for pain, wounds, injuries, and other conditions. This method is different from conventional laser surgery (using hot lasers), which is used as a proven treatment for some cancers. According to the American Cancer Society, hot lasers may be used to shrink or destroy tumors on the skin or on the surfaces of internal organs. They are sometimes used to remove colon polyps or tumors that are blocking the windpipe, colon, or stomach, and they

Cold Laser and LED Therapy

can help relieve symptoms of cancer, such as bleeding.

OSRAM Opto Semiconductors (Sunnyvale, CA) manufactures a visible red laser that emits red laser light with a wavelength of 650 nanometers for medical applications. The laser is used as a source of radiation for the soft laser and consumer sectors. The red laser is designed for continuous wave operation with a lateral stripe width of 100 μm and an optical output of 500 mW. At an ambient temperature of 20°C its typical lifespan is more than 4,000 hours, which is four times the minimum requirement for medical applications of 1,000 hours. Cooling is provided by a small copper heat sink.

This source of radiation is used for professional medical applications such

as photodynamic cancer therapy and ophthalmology. In cancer therapy, the laser's wavelength of 650 nm is effective in combination with a particular drug. In soft laser equipment, it is used in laser therapy and biostimulation. The radiation can have a regenerative effect for self-healing and reduce pain and swelling, such as in sports injuries.

Visit <http://info.hotims.com/22930-173> for more information.

Apollo Physical Therapy Products (Redwood City, CA) provides therapeutic lasers with 2000-mW, 500-mW, or 250-mW laser probes that require treatment times of as little as 1 to 2 minutes. The lasers are used to treat a variety of pain syndromes, injuries, wounds, fractures, and neurological conditions. The

company's portable laser system is designed for field use or multi-office use. A Desktop Laser System for clinic environments holds two probes, allowing the user to switch from pain treatments to laser acupuncture. The Apollo 2009 Laser System enables user-controlled treatment times selectable between 10 seconds and 2 minutes and is FDA cleared.

Visit <http://info.hotims.com/22930-174> for more information.

Cynosure (Westford, MA) offers an over-the-counter laser that is cleared for laser cellulite treatment and temporary cellulite reduction. The TriActive Cellulite Workstation smooths and tones the skin anywhere on the body. The system uses a mechanical massage/rhythmic aspiration technique that distends the skin in various directions to enhance microcirculation, thereby increasing skin elasticity and improving lymphatic drainage. Six diode lasers penetrate tissue to stimulate fibroblasts for collagen production.

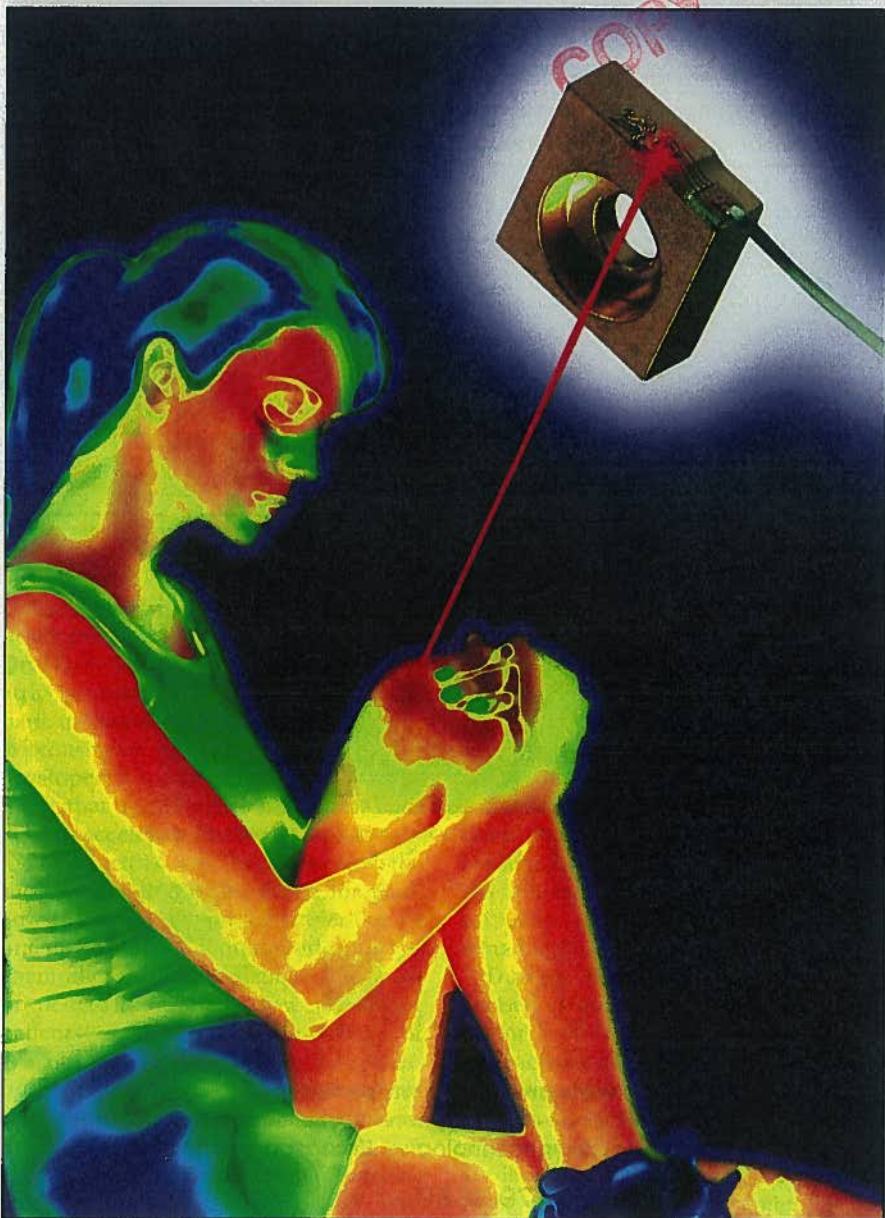
TriActive also features therapeutic massage functionality for relief of muscle pain. The system can be used in combination with other therapies to enhance the outcomes of surgical and non-surgical procedures such as liposuction and dermal fillers.

Visit <http://info.hotims.com/22930-175> for more information.

The FDA and Lasers

Some lasers have been cleared by the U.S. Food & Drug Administration (FDA) for medical uses. Usually, the FDA gives manufacturers general surgical clearances, but in order to promote the laser for a specific surgical procedure, manufacturers must first provide the FDA with clinical evidence that their lasers are safe and effective for that specific procedure. States regulate who can use lasers for various therapeutic procedures.

Biostimulation lasers, cold lasers, or laser acupuncture devices, were cleared for marketing by the FDA as adjunctive devices for the temporary relief of pain. All laser devices distributed for both human and animal treatment in the U.S. are subject to mandatory performance standards that specify the safety features and labeling that all laser products must have in order to provide adequate safety to users and patients. Certification of a laser product means that each unit has passed a quality assurance test and that it complies with the performance standard.



OSRAM Opto Semiconductors' visible semiconductor lasers are used in medical applications and for mobile soft laser equipment that can be used for personal pain therapy. (OSRAM press picture)