

Dear Patient,

We wanted to share some good news.

Many of our citizens are plagued with joint and muscle pain. Some rely on pain medications to keep moving. This has been dangerous, highly addictive, and lethal for many.

The Willow Curve[®] is a professional grade digital health device for joint and muscle pain. It helps to reduce the pain while helping increase blood flow in the affected areas. Over 50,000 patients on the Willow Curve to keep them moving.

Now, Medicare members and soon others who have third party insurance can receive their Willow Curve with nothing out of pocket to be able to receive safe and effective digital pain reduction and improved quality of life. It is paid for by The Centers for Medicare and Medicaid (CMS) and soon other medical insurance companies.

How to Receive Your Willow Curve with No Out of Pocket Cost.

Step 1: Print the next page and the scientific information pages and take them to your physician.

Step 2: Your physician can study the information to make sure the Willow Curve is right for you.

Step 3: Then, your physician writes a prescription for a Willow Curve[®], and you or your physician faxes, mails, or emails the prescription to Physician's Technology.

- a. **Mail:** Physician's Technology, LLC, 23 East Front Street, Monroe, MI. 48161
- b. **Fax:** 734-241-5065 (Attention: D. Smith)
- c. **eMail:** dsmith@willowmd.com

Step 4: Physician's Technology validates your insurance eligibility to receive a Willow Curve for you with no out of pocket cost. It is shipped directly to your address. It includes simple suggestions for use.

If you have questions about this program, please call our **Help Desk at (888) 988-0652**. Thank you.

Dear Physician,

Your patient is suffering from a painful joint and or muscle condition limiting their functional ability and their quality of life. As Medical Director of Physician's Technology, LLC, a medical device company dedicated to developing and advancing safe, effective and non-invasive digital technology for joint and muscle pain, I am writing to appraise you of the technology. This unique FDA registered, patented medical device is marketed as the Willow Curve®.

The Willow Curve is a three-module computer with sensory, CPU, and digital therapeutic modules that evaluate the condition of the tissue, calculates a customized digital prescription, and delivers it to the skin surface and deeper tissues. All the modules work in real time concert with each other, and include data collection, CPU reporting, and digital therapeutic prescriptions which change thousands of times per second. Double blinded, controlled, studies, physicians, and patients (over 54 thousand) have validated consistent and favorable Willow Curve results. As a result, The Willow Curve has been awarded a 5-five-year Federal GSA contract to supply Willow Curves at no out of pocket cost to U.S. Veterans in need of this advanced technology. The Willow Curve has also been assigned the **Level II HCPCS Code E0221 by Medicare.**

The studies, and consultation with our Medical Department Physicians are always available to you. We are requesting that you consider honoring your patient's request to try this technology. Successful use of the Willow Curve obviates and minimizes the need for your patient to rely on medications that have potential adverse, addictive, and lethal side effects.

With your permission and a prescription (sample attached) your patient can have their Willow Curve shipped to your office or their home with no out of pocket cost. A scientific summary of Willow Curve® Specifications is attached and we invite you to visit www.willowcurve.com

Regards,



Ronald S. Shapiro, MD, PhD, FACP
Medical Director
rshapiro@willowmd.com
(734) 241-5060 Ext. 207



WILLOW CURVE® PRESCRIPTION
HCPCS Code: E0221

Date _____ DOB _____

Patient Name _____

Patient Address _____

Diagnosis _____

Please Dispense One Willow Curve device. Use as directed.

Order From: Physician's Technology, LLC

Mail: 23 E. Front St.-Monroe, MI. 48161

eMail: dsmith@willowmd.com

Fax: (734) 241-5065

Physician Name _____

Physician Phone _____

Physician Address _____

Physician EIN# _____

Physician Signature _____

Sample Prescription



PHYSICIAN'S TECHNOLOGY, LLC

23 East Front Street
Monroe, Michigan 48161
(734) 241-5060
www.willowcurve.com

SCIENTIFIC SUMMARY OF WILLOW CURVE® SPECIFICATIONS

The Willow Curve® uses the NINS® (non-invasive neurovascular stimulation) operating system, which is housed in the product as a type of biomedical computer. In short, the device emits dynamic particles of light (photons or photonic energy) and heat (thermal kinetic energy) to a treatment area of the body of the user. The photonic energy (employing LLLT) uses a variety of multiple wavelengths (e.g., particles in the visible spectrum and particles from the invisible spectrum). Specifically, the Willow Curve® uses light-emitting diodes ("LEDs") which emit output in both the visible (red) 630 nm range, and infrared 875 nm range (which is not visible to the naked eye). Importantly, the wavelength varies slightly based on the mode of the device, captured sensory data from the skin surface and tissues below, and the distance of measurement from the diodes. The actual ranges for the infrared output, based on product testing, are 887 nm to 915 nm.

Particles are employed based on a variety of parameters, including, but not limited to: magnitude, Joules, patterns, sweeps, cascades, duty cycles, frequencies (which can range from 292 times per second to over 4,000 times per second), alternations, and time. The parameters of the photonic energy transmission can change thousands of times per second. Additionally, thermal kinetic energy properties can be manipulated through multiple cycles, deployed in changing joule packets, and/or delivered in concert with the photonic components. Thermal kinetic energy is dynamic, in contrast to static heat. While most diodes of the Willow Curve® are pulsed, others are continuous, with their expression varying depending on the program being utilized by the software; their output is modified by nine different parameters.

In addition, the Willow Curve® has passed Federal Communications Commission ("FCC") testing (47 C.F.R. § 15.109(a) and 47 C.F.R. § 15.107(a)) for radio frequency devices conducted limits and radiation emission limits. It has also passed testing for Canada's ICES-003, Issue 5 (technical requirements relative to radio noise generated by Information Technology Equipment).

With regard to FDA medical device clearance, the FDA cleared the SpectroPad (marketed as the Anodyne) in 1994. The SpectroPad was the first generation of the Willow Curve® and was cleared for "...heat therapy, i.e. temporarily relieves minor pain, stiffness, and muscle spasm" and also "[t]emporarily increases local blood circulation." We note that Physician's Technology does not currently have a 510(k) for the Willow Curve® because the company was advised by the FDA, in writing in 1998, that it did not need one. Moreover, the FDA just recently issued a final notice that it is exempting these devices (therapeutic heating infrared lamps (under product code ILY and 21 C.F.R. § 890.5500)) from the requirements to submit a 510(k). 82 Fed. Reg. 31,976, 31,980 (July 11, 2017). **Willow Curve has been issued U.S. Federal Government (GSA) Contract (Contract number:V797D-70038) to provide Willow Curve devices to government employees and Veterans paid for by the government, and The Department of Health & Human Services Centers for Medicare and Medicaid Services has assigned DME code (E0221) to the Willow Curve for Medicare payment.**

This is not surprising given that the safety of LLLT is well-established. Indeed, with diodes such as those on the Willow Curve®, the power of the light is lower than those needed to produce anything more than safe minimal heating of tissue. For example, Nakaji *et al.* (2005), assessed the long-term effects of LLLT in 1,087 patients who were treated by LLLT at a Japanese clinic from April 1992 to August 1995. Questionnaires were sent to subjects in fall of 1996, thus demonstrating a significant amount of time had passed since treatment. After reviewing the 662 replies, the study concluded that LLLT could be "considered safe, effective, and side-effect-free." Similarly, the Abrisham *et al.* (2011) study, evaluated the effect of LLLT with exercise on shoulder pain in 80 patients. The study noted that none of the participants reported any adverse reaction or side effects. Furthermore, Physician's Technology has not received any reports of serious adverse events related to use of the product.

LOW-LEVEL LASER LIGHT THERAPY BACKGROUND INFORMATION

As mentioned above, the red and infrared output emitted from the Willow Curve® is a type of low-level laser therapy ("LLLT"). LLLT involves exposing cells or tissue to low levels of red and near infrared ("NIR") light. It is referred to as "low level" because of its use of light at lower energy levels as compared to other forms of laser therapy (e.g., those that are used for ablation, cutting, and thermally coagulating tissue). With LLLT, the energy levels used are lower than those needed to produce heating of tissue.

Essentially, light is packets of electromagnetic energy, which also have a wave-like property. Wavelength is measured in nanometers and is visible in the 400 - 700 nm range and also determines how the light will be absorbed. Typically, LLLT devices use wavelengths in the 600-1000 nm range. All LLLT devices work in a similar manner, namely by inducing photobiomodulation

LLLT has been used for years to reduce neurogenic pain, reduce inflammation, treat hair loss, promote wound healing, and treat acne, among other therapeutic treatments. LLLT has been the subject of numerous studies demonstrating its many health and cosmetic benefits. LLLT came into being in its modern form soon after the invention of the ruby laser in 1960 and the helium- neon laser in 1961. LLLT's benefits were first discovered inadvertently in 1967 by researcher Endre Mester of Semmelweis University in Budapest, Hungary. In a study conducted to determine whether laser radiation causes cancer in mice, Mester divided the mice into two groups, shaved the hair from the mice's backs, and administered low-powered ruby laser treatment to one of the groups. The mice treated with lasers did not develop cancer, but their hair grew back more quickly than mice in the untreated group. He then demonstrated the laser's ability to stimulate wound healing in mice, and then to stimulate healing in non-healing skin ulcers. Since then, LLLT has developed into a therapeutic procedure that is used in three main ways: to reduce inflammation, edema, and chronic joint disorders; to promote healing of wounds, deeper tissues, and nerves; and to treat neurological disorders and pain.

The precise biochemical mechanisms underlying the therapeutic effects of LLLT are not yet well established. However, according to Chung *et al.*, it appears that LLLT has a wide range of effects at the molecular, cellular, and tissue levels. In addition, its specific modes of action may vary among different applications. Within the cell, there is strong evidence to suggest that LLLT acts on the mitochondria to increase adenosine triphosphate ("ATP") production, modulation of reactive oxygen species ("ROS"), and the induction of transcription factors. Several transcription factors are regulated by changes in cellular redox state. These transcription factors then cause protein synthesis that triggers further effects downstream, such as increased cell proliferation and migration, modulation in the levels of cytokines, growth factors and inflammatory mediators, and increased tissue oxygenation.

At the most basic level, LLLT acts by inducing a photochemical reaction in the cell, a process referred to as biostimulation or photobiomodulation. When a photon of light is absorbed by a chromophore in the treated cells, an electron in the chromophore can become excited and jump from a low-energy orbit to a higher-energy orbit; various cellular tasks can then use this stored energy. There are several pieces of evidence that point to a chromophore within mitochondria being the initial target of LLLT. Radiation of tissue with light causes an increase in mitochondrial products such as ATP, nicotinamide adenine dinucleotide + hydrogen ("NADH"), protein, and ribonucleic acid ("RNA"), as well as a reciprocal augmentation in oxygen consumption, and various in vitro experiments have confirmed that cellular respiration is upregulated when mitochondria are exposed to a helium-neon ("HeNe") laser, a recognized form of LLLT, or other forms of illumination.

In particular, immune cells appear to be strongly affected by LLLT. Mast cells, which play a crucial role in the movement of leukocytes, are of great importance in inflammation. LLLT is able to trigger mast cell degranulation, which results in the release of the pro-inflammatory cytokine TNF- α from the cells. This leads to increased infiltration of the tissues by leukocytes. LLLT also enhances the proliferation, maturation, and motility of fibroblasts, and increases the production of basic fibroblast growth factor. Lymphocytes become activated and proliferate more rapidly, and epithelial cells become more motile, allowing wound sites to close more quickly. The ability of macrophages to act as phagocytes is also enhanced under the application of LLLT.

Additionally, LLLT has been shown to cause vasodilation by triggering the relaxation of smooth muscle associated with endothelium, which is highly relevant to the treatment of joint inflammation. This vasodilation increases blood circulation and the availability of oxygen to treated cells, and also allows for greater traffic of immune cells into tissue. These two effects contribute to accelerated healing. Nitric Oxide ("NO") is a potent vasodilator via its effect on cyclic guanine monophosphate production, and it has been hypothesized that LLLT may cause photodissociation of NO, not only from cytochrome c oxidase ("CCO"), but also from intracellular stores such as nitrosylated forms of both hemoglobin and myoglobin, leading to vasodilation. As described below, LLLT's effects on vasodilation are believed to act via increased NO.

Published studies and references documenting the scientific information presented above are available upon request from Willow Labs LLC Medical Department.

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