biowave

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Biowave PENS

BiowavePRO System with Biowave® Percutaneous Electrodes – Percutaneous Neuromodulation Pain Therapy Treatment (formerly called Deepwave Percutaneous Neuromodulation Pain Therapy)

PAIN MANAGEMENT PROCEDURE DESCRIPTION

PENS is Significantly Better than TENS

The transmission of pain is conducted by the body's central nervous system. There are different types of nerve fibers, which perceive and transmit pain. By interrupting the transmission of pain signals in the nerves, pain signals do not reach the brain; therefore, pain is not perceived.

The biggest obstacle relative to delivering electrical signals into the body to reach nerve fibers is the impedance and capacitance of skin, which acts as a barrier. This is the fundamental reason that transcutaneous electrical stimulation (TENS) does not work – electrical signals only travel across the surface of the skin and do not reach nerve fibers. Percutaneous Electrical Nerve Stimulation (PENS) devices use a group of individual needles or an array of needles to pass through the outer layers of skin (piercing the barrier) which provides a direct conductive pathway through skin into deeper tissues. Numerous published clinical studies in peer-reviewed journals support and endorse the fact that PENS provides greater and longer lasting pain reduction than TENS. In some clinical studies, PENS is also referred to as Percutaneous Neuromodulation Therapy or PNT.

Biowave is FDA Cleared as PENS

The BiowavePRO System, with Biowave Percutaneous Electrodes ("Biowave PENS") is the only Percutaneous Electrical Nerve Stimulation (PENS) medical device available in the U.S. market that is cleared by the FDA. Biowave PENS was formerly called Deepwave Percutaneous Neuromodulation Pain Therapy.

The FDA's clearance of Biowave PENS was based on a predicate PENS medical device made by Vertis Neuroscience. The Vertis PENS device utilizes ten 3-centimeter long needles to deliver electrical stimulation down to nerves carrying pain signals.

The FDA's marketing clearance for Biowave PENS stated that Biowave PENS is substantially equivalent to Vertis PENS and approved Biowave PENS to be used for the following indications:

- Symptomatic relief of chronic, intractable pain, post surgical and post-traumatic acute pain;
- Symptomatic relief of post-traumatic pain;
- Symptomatic relief of post-operative pain.

Biowave PENS Percutaneous Needle Array is More Advanced Than Traditional Array of 10 PENS Needles

The Biowave PENS Percutaneous Needle Array and the Vertis Neuroscience PENS needle array are both percutaneous electrode arrays designed to deliver electrical energy through the skin layer into deeper tissues inside the body. Both the Biowave and the Vertis PENS needle arrays are sterile, single use percutaneous electrodes made from surgical grade biocompatible stainless steel, and both are gamma sterilized.

The Biowave PENS Percutaneous Needle Array is a sterile, single use percutaneous electrode comprised of a 1.5 inch diameter disk, made from 316L surgical grade stainless steel, from which an array of 1014 needles are etched and formed to stand at a 90-degree angle from the base of the array. Each needle is 0.74 millimeters in length and has a rectangular cross section of 0.203 millimeters by 0.051 millimeters. The Biowave PENS Needle Array has a total needle surface area of approximately 3.3 cm^2 that penetrates through the skin. The entire 1.5 inch diameter stainless steel array sits within the center of a 2.5 inch diameter hydrogel based percutaneous electrode.

The Vertis PENS Needle Array contains ten 3-centimeter long needles with a diameter of 210 μm. The Vertis Needle Array has a total needle surface area of approximately 2.0 cm^2 that penetrates through the skin. The 10 Vertis needles are connected via a template that allows for proper positioning of the 10 needles in the lumbar or cervical spine.

Electrically, the Biowave PENS Needle Array has about 1.7 times the needle surface area of the Vertis PENS Needle Array, through which current is conducted passed the skin layer into the body. At a given current, the Biowave PEA operates at a lower current density so it is safer, however the Biowave PENS active electrical field generated captures a much greater volume of tissue inside the body, approximately 115.8 cm^3 versus only about 10.0 cm^3 for the traditional Vertis PENS Needle Array.

The Biowave PENS Needle Array therefore allows over 10 times the volume of tissue inside the body to be treated by the active electrical field versus the 10 individual traditional Vertis PENS needles.

How does Biowave PENS work?

The BiowavePRO System with Biowave Percutaneous Electrodes (Biowave PENS), uses a patented electrical signal technology allowing delivery of electrical signals through skin into deep tissue that encompass the pain site and blocks the transmission of chronic, acute or post-operative musculoskeletal pain. Biowave PENS can be used to treat pain in the lumbar, thoracic, and cervical spine, hip, shoulder, knee, elbow, wrist, hand, ankle, and foot.

The BiowavePRO device delivers a summation of two alternating current high frequency sinusoidal waveforms at 3858 Hz and at 3980 Hz into a Biowave PENS Percutaneous Needle Array placed directly over the source of pain. The Biowave Percutaneous Electrode is a sterile single-use electrode utilizing a patented technology comprised of 1014 needles, 0.74 mm in length arranged in an array within a 2.5 inch diameter patch. The needles pierce through the skin barrier and provide a direct conductive pathway into deeper tissue bypassing the impedance of the skin.

The two summed high frequency waveforms pass through the Biowave PENS Needle Array and into the body. Polarized tissue including nerve fiber membranes like the C-fiber (pain fiber), A-delta fiber (sensory fiber) and muscle tissue, that lie within a 3 inch diameter hemisphere beneath each Needle Array, act like nonlinear devices, and cause a mathematical multiplication of the two high frequency waveforms. The result is that a new spectrum of signals form inside the body, one of which is a low frequency 122 Hz alternating current electrical field in approximately a 3-inch diameter hemisphere (115.8 cm^3) beneath each percutaneous electrode, that interrupts the transmission of pain impulses by preventing action potential propagation along C-fibers and by inducing hypoesthesia (light numbness) in A-delta fibers (a mechanism similar to local chemical anesthesia, except without any deleterious side effects).

Determining Optimal Location for Insertion of the Needle Array

Knowledge of the diagnosis, type of pain condition and the manner in which the pain presents is critical for determining the optimal location for insertion, and the need for one or two Biowave PENS Needle Arrays. Physician training on the protocols for electrode placement for every location on the body and type of pain condition are important and critical for obtaining optimal treatment outcomes for the patient.

When two Needle Arrays are used, one is placed directly over the location of where the pain presents and one over the location, based on the physician’s diagnosis, which is likely the source of the pain.

When one Needle Array is used, one is placed directly over the location of where the pain presents or over the source of the pain. The location of insertion depends upon the diagnosis as well as the location on the body being treated, for example, spine versus extremity.

Skin Preparation for the Needle Array

The skin must be properly cleaned and disinfected prior to insertion of the Biowave PENS Needle Array. Cleaning the skin with alcohol or a similar disinfectant is required prior to insertion of the needle array. The skin must be completely dry before application of the needle array. The Needle Array must not be placed over wet alcohol.

Insertion of the Needle Array

Proper insertion of the Biowave PENS Needle Array is critical to positive treatment outcomes. The patient must be in a supported position, typically prone or supine on a patient table. Once the proper location for insertion has been determined and the skin properly cleaned and disinfected, the Biowave PENS Needle Array must be carefully removed from the plastic cup on which it resides. The physician must carefully peel back the cup slowly along the perimeter of the Needle Array making sure not to kink or dent any of the 1014 needles in the array. Once the protective cup is removed, the sterile needle array is carefully placed over the preselected and disinfected location. The hydrogel on the perimeter of the array temporarily holds the PENS Needle Array in place. The physician must then use both thumbs and place over 20 pounds per square inch of pressure, exactly perpendicular to the entire backside of the Needle Array. No pressure can be placed at an angle to the back of the Needle Array as the needles may bend and stay only on the surface of the skin. The physician must ensure that all 1014 needles have been inserted into and through the skin, by applying pressure to the entire back surface of the Biowave PENS Needle Array.

Operation of the BiowavePRO Device

Once the Needle Arrays have been inserted into the patient, the physician will instruct the patient on how to control the intensity on the BiowavePRO device during the duration of the 30-minute treatment.

The patient controls their own comfort level adjusting the intensity by pressing a PLUS button or a MINUS button on the face of the device. The first time the intensity button is pressed, the countdown timer in the lower center of the LCD display will begin counting down. For each press of the Plus (+) Button, the large intensity number in the middle of the display will increase by 0.5%. The patient should continue to increase the intensity and pain control effect until a strong tingling/pressure sensation is felt in the 3-inch diameter hemisphere beneath the Biowave PENS Needle Array(s). This is typically at an intensity reading of 15 - 20% of maximum voltage.

The physician explains that the body adapts quickly to the electric field in the first two minutes of treatment and the edge of the sensation felt by the patient will begin to diminish within several seconds. The patient should then repeatedly press the PLUS Button to further increase the intensity so that they feel a very strong, but comfortable tingling/pressure sensation. Again their body will adapt to the electric field; however more slowly this time, causing the sensation to slightly diminish over a longer period of time. The patient should repeat this process of increasing the intensity until the sensation beneath and surrounding the Needle Array remains strong and is no longer diminishing.

This is considered the therapeutic level.

Most patients advance in the first five minutes to an intensity level of between 15% and 30%, and may end up at a maximum intensity of between 30% and 60%. The maximum intensity reached depends upon several factors including the nature of the pain condition, location on the body being treated (for example spine versus extremity) and physiology of the patient. When the countdown timer reaches 0 minutes and 0 seconds, the intensity automatically is reduced to zero.

Most patients report that Biowave PENS feels like a deep tingling or “pins and needles” type sensation, and at higher intensities, may feel like a very intense deep muscle massage. Patients are encouraged to increase the intensity up to a very strong, but tolerable sensation. Generally, the Biowave procedure is well tolerated.

Post Treatment Procedure

The physician must carefully and slowly remove the Biowave PENS Needle Array from the patient’s skin. Both electrodes must be discarded into a Sharp’s Disposal.

The patient’s skin will have a pink circle underneath the Needle Array with a dimple pattern showing the location of the insertion of the 1014 needles. Typically 5 to 10 of the needle locations will have a small drop of blood at the surface of the skin. The physician should clean the skin with sterile gauze that may be left taped over the treatment location for one to two hours until the treatment sight resolves on its own. This is similar to the procedure following an injection.

Clinical and Reported Patient Results

Approximately 80% of patients respond to the Biowave PENS treatment. Patients that respond experience pain relief during and immediately following the treatment as well as an improvement in function including an increase in range of motion, reduction of stiffness and a reduction in muscle spasm.

Clinical studies show and physicians and patients report an average 75% reduction in pain, and that the patient’s pain relief improves even further over four to six hours following the treatment. Patients usually experience pain relief and improved function for 24-48 hours following the treatment and without the side effects that are common to drugs, injection therapies, surgery and implanted devices. Empirically, multiple treatments have provided a cumulative benefit for patients and Biowave has found that 6 – 12 treatments performed over a 2 – 6 week time frame can provide significant long lasting pain relief.

Patient’s Activity Level Post Procedure

There are no limits to the patient’s activity after receiving a BiowavePRO treatment with Biowave PENS. However, with less pain, patients should be careful not to perform strenuous activities that might have caused the pain in the first place.

Determination for Further Biowave PENS treatments

If the patient feels less pain and has a positive response to the first treatment, their physician may recommend that they return for at least 5 additional treatments, preferably 2 to 3 times per week following the first treatment. Physicians and patients report that multiple treatments provide a cumulative type effect. If the patient is among the small number of people who experience no benefit from a treatment, then it is unlikely that the doctor will repeat the treatment.

Following 6 successful Biowave PENS treatments, many patients may remain at a new lower pain level. Depending upon the nature of the pain condition and if the physician believes it is medically necessary for the patient, the physician may choose to have the patient return for additional Biowave PENS treatments should the treatments continue to help reduce and manage the patient's pain. In some instances, patients may reaggravate their pain condition at a later point in time and the physician may direct the patient to return for another series of 6 Biowave PENS treatments.

Contraindications for Biowave PENS

Biowave PENS cannot be used if the patient has any of the following conditions: cardiac pacemaker or defibrillator, stainless steel allergy, suspected or diagnosed heart problems or epilepsy. Biowave PENS Needle Arrays cannot be placed on the front or side of the neck, on the head or across the thoracic volume (not over the heart on the front and over the heart on the back).

Biowave PENS Needle Arrays cannot be placed over swollen, infected, or inflamed areas or over skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, or over cancerous lesions. Needle Arrays also should not be placed over staples on the surface of the skin that have not yet been removed from a healed incision.

Biowave PENS Needle Arrays may be placed over scar tissue and used with all orthopedic hardware including total joint replacements, pins, screws, anchors, clips, and plates.