Revised April 2017

Percutaneous Electrical Nerve Stimulation
for the Treatment of Chronic, Acute and Postoperative Pain

biowavePENS®

quick reference

for Biowave Percutaneous Electrodes

There are 5 buttons that control the device:

1. Power ON/OFF button
2. PLUS (+) button to increase intensity or increase treatment time
3. MINUS (–) button to decrease intensity or decrease treatment time
4. TIME button to enter TIME mode in order to change treatment time
5. OK button to accept and set a new treatment time

DIRECTIONS FOR USE - PENS TREATMENTS

1. Use an alcohol prep to clean the skin in the location percutaneous electrode(s) are to be placed. Dry the skin with sterile gauze.
2. See Electrode Placement Examples inside to determine correct percutaneous electrode placement location.
3. Carefully peel off percutaneous electrode(s) along perimeter away from plastic cup. Place electrodes on skin over pain site and/or over source of pain. Using both thumbs press firmly with over 10 lbs of force perpendicular to back surface of electrode to ensure all microneedles pass through outer layers of skin.
4. Attach leadwire cable to electrodes. Either blue leadwire connector can be attached to either electrode.
5. Align red dot on metal connector at end of leadwire cable so it is facing up. Gently slide metal connector into device so it clicks in place.
6. Turn on device. Start up screen should read 0.0%
7. Patient starts treatment by pressing the PLUS (+) button.
8. Patient continues to press the PLUS (+) button throughout the treatment so a steady strong but comfortable tingling and pressure sensation is felt under the electrodes covering the pain sites.

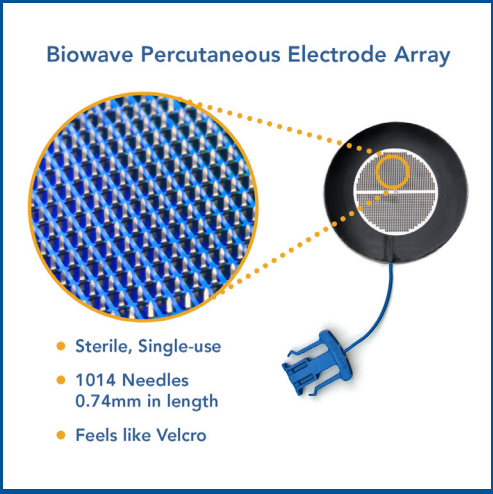
See User's Manual for detailed instructions.

Turn ON Biowave
Turn OFF Pain

Biowave Percutaneous
Electrodes

The BiowavePENS Percutaneous Electrical Nerve Stimulation System is comprised of a BiowavePRO neurostimulator and Biowave Percutaneous Electrodes.

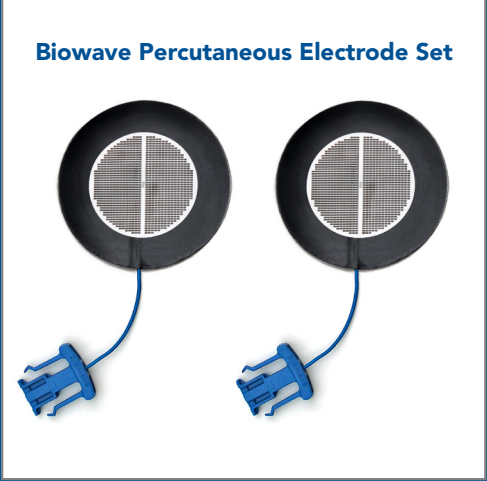
Biowave Percutaneous Electrode Arrays are sterile, single-use and comprised of over 1000 needles that are 0.74 mm in length within a 1.5" diameter array. These electrode arrays feel like Velcro to the touch and are designed to provide a direct conductive pathway through skin, bypassing the impedance of skin, and allowing the therapeutic electrical field to form in deep tissue encompassing pain nerves. BiowavePENS may only be used with Biowave Percutaneous Electrodes.



B-Set BWEP01-B

The Biowave Percutaneous Electrode Set is comprised of two 2.5" diameter round sterile, single-use percutaneous electrodes for treating:

- Two locations of pain,
- One location of pain and the source or orgin of the pain,
- Pain over a large area

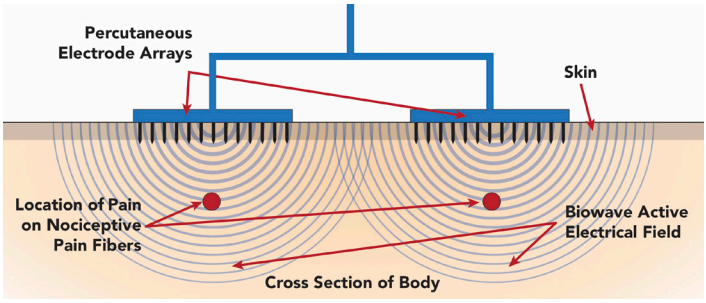


See opposite page for percutaneous electrode placement examples

WARNING: Electrodes must not touch each other.

Electrode Placement Rationale For Percutaneous Electrodes

BiowavePENS percutaneous electrode array placements are different from conventional surface electrical stimulation. The active therapeutic electrical field forms in a 3.5 inch diameter hemisphere (volume of tissue the size of half of a grapefruit) beneath and surrounding each electrode, not along the surface of the skin between the electrodes - see illustration below.



As a result, electrodes need to be placed either:

(1) directly over two locations of pain;

(2) over one location of pain and the source of the pain; or

(3) spaced one inch apart to cover one small or large location of pain.

Electrodes are independent of one another and there is no maximum distance between the two electrodes. Therefore two distinct pain sites can be treated simultaneously. If the two electrodes are placed 1.0 inch apart from one another, the pair can be used to treat one larger volume of tissue. For a neuropathic condition like a radiculopathy, one electrode is placed over the source of the pain, 0.5 inches to the right or left of the spine depending on the direction the pain is radiating. For example, for a right side radiculopathy, one electrode is placed 0.5 inches to the right of the spine to modulate the pain signals traveling in that direction. The second electrode is placed in the most proximal location that the pain first presents, for example, on the buttock.

Body Position During Treatment

The body should remain in a static position during the treatment. Generally, the tissue being treated should be taut or in a stretch position. Generally, sitting in a supported position in a comfortable chair is best for most treatment locations on the body.

Low Back and Buttocks

The torso should be at approximately 90 degrees to the legs causing tissue in the low back and buttocks to be more taut. If necessary, the patient can be in a prone position during the treatment.

Hip and Groin

Lying supine with the legs straight is best for hip or groin treatments.

Neck, Shoulders and Thoracic Back

Generally, sitting is the most comfortable position during cervical, thoracic and shoulder treatments. For neck treatments, the head should be bent forward to keep the tissue on the back of the neck more taut.

Knees

The knee should be bent at approximately 90 degrees. This angle provides the strongest sensation in the knee during the treatment which will yield the best outcome. For posterior knee treatments, the knee should be kept straight so the tissue on the posterior of the knee is more taut.

Ankles and Feet

Sitting with the foot pressing on a flat surface is the best position. The foot should be at approximately 90 degrees to the tibia. If necessary, the foot may be elevated during treatment.

Elbows, Wrists, Hands and Fingers

The arm should rest at the side of the body with the elbow bent at a small angle. The patient should hold a rolled up towel to keep their hand and fingers in a comfortable position during the treatment.

Treatment Regimen Protocol

Biowave's Preauthorization Service typically preauthorizes up to 12, 30-minute treatments over a 30 day period. Multiple treatments may provide a cumulative benefit. Additional treatments may be beneficial. The same pain site location may be treated up to two times per day with each 30-minute treatment separated by at least 8-hours.

Intensity Range

Patients should increase the intensity based on sensation (not an intensity number) to a level that is as strong as possible but still comfortable. The body adapts to the electrical field very quickly over the first 5 minutes and then less so over the remainder of the 30-minute treatment. As hypoesthesia is induced in the volume of tissue beneath the percutaneous electrodes and the sensation diminishes, patients should continue to increase the intensity level with individual presses of the PLUS (+) button.

Generally, patients should try to reach a minimum intensity level of 20%. Some patients may tolerate more, some less. Certain parts of the body may be more sensitive to stimulation and therefore harder to achieve higher intensity levels. **The typical maximum intensity level reached during the treatment ranges from 20% - 50%.**

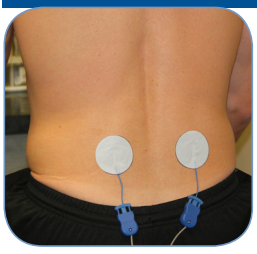
Motion During Treatment

The sensation from the treatment is a deep, smooth, strong tingling and pressure sensation. Generally patients should remain in a static position during the treatment. Motion may cause a stronger or weaker sensation and will cause the location of the electrical field to shift slightly internally. Shifting of the electrical field is most prevalent when treating upper and lower extremities.

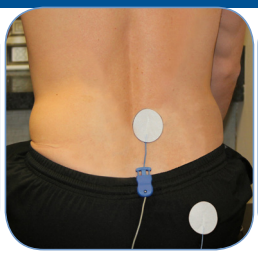
The goal is to have the patient very gently articulate the joint at the treatment location to shift the sensation caused by the electrical field so that it focuses directly onto and encompasses the primary pain location. This is a fine tuning of the treatment that will provide the best treatment result.

Percutaneous Electrode Placement Examples

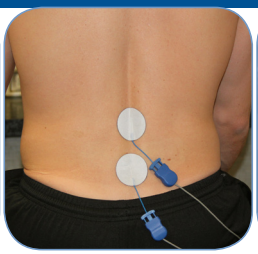
Lumbar



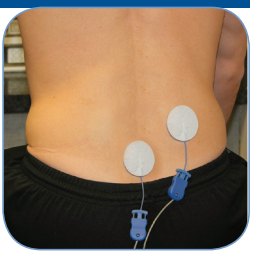
Bilateral Low Back Pain



Radiculopathy - Electrodes Over Source and Proximal Pain Site

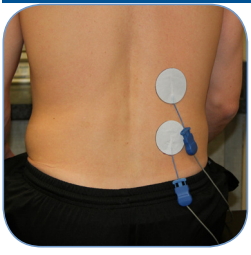


Low Back Pain Focused Over One or Multiple Discs



Unilateral Low Back Pain Focused on One Side of Spine

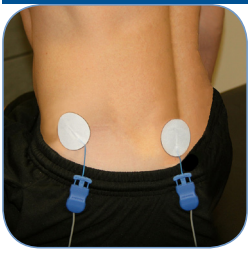
Lumbar



Pain Over Large Area (e.g. Rotational Strain)

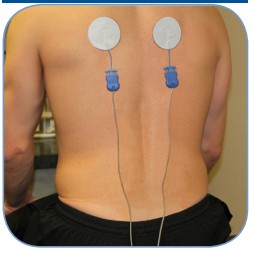
Sacroiliac (SI) Joint Pain

Hip



Hip Pain

Thoracic



Bilateral Thoracic Pain

Cervical

Cervical or Neck Pain

Cervical or Neck Pain In Two Locations

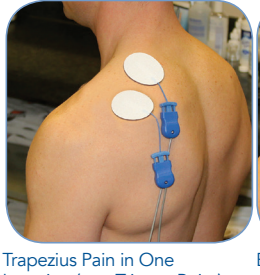
Radiculopathy – Electrodes Over Source and Proximal Pain Site

Neck Pain Over Several Cervical Discs

Cervical

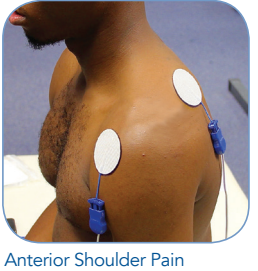
Bilateral Neck Pain

Shoulders



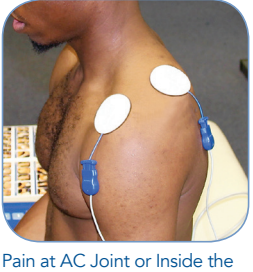
Trapezius Pain in One Location (e.g. Trigger Point)

Bilateral Trapezius Pain

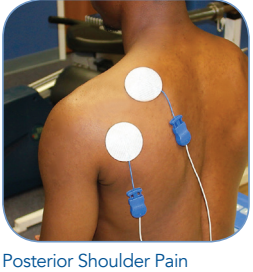


Anterior Shoulder Pain (e.g. Biceps Tendinitis)

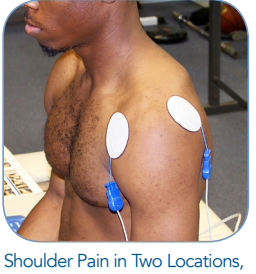
Shoulders



Pain at AC Joint or Inside the Shoulder (e.g. AC Sprain)



Posterior Shoulder Pain (e.g. Infraspinatus Strain)



Shoulder Pain in Two Locations, Adhesive Capsulitis

WARNING: Electrodes must not touch each other.
See back cover for electrode description.

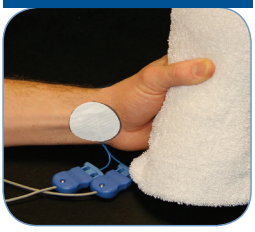
Elbows

Lateral Elbow Pain
(e.g. Lateral Epicondylitis)

Medial Elbow Pain
(e.g. Medial Epicondylitis)

Posterior Elbow Pain
(e.g. Triceps Tendinitis)

Wrists



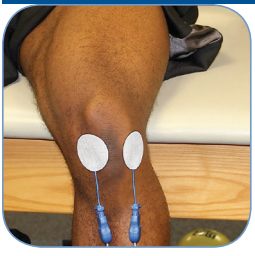
Anterior Wrist Pain (e.g.
Sprains, Strains, Tendinosis,
Carpal Tunnel Syndrome)

Wrists, Hands & Fingers

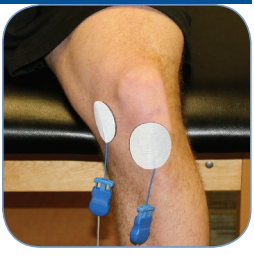
Posterior Wrist Pain (e.g.
Sprains, Strains, Tendinosis)

Pain at Metacarpal Phalangeal
or Interphalangeal Joint

Knees

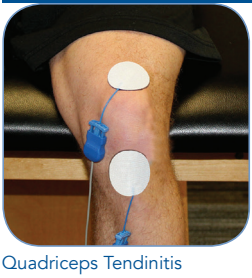


Central Knee Pain (e.g. OA,
Bursitis, Meniscus, ACL Sprain)

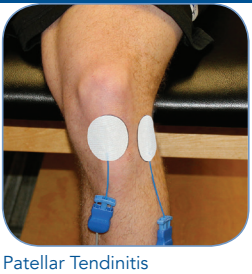


Medial Knee Pain (e.g.
OA, Bursitis, MCL Sprain)

Knees

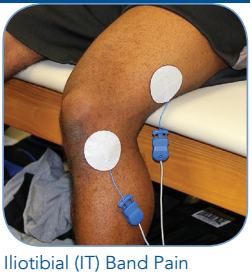


Quadriceps Tendinitis



Patellar Tendinitis

Lateral Knee Pain (e.g. OA,
Bursitis, LCL Sprain)



Iliotibial (IT) Band Pain
in One or Two locations

Knees

Pain Throughout Entire Knee
(e.g. Total Knee Arthroplasty)

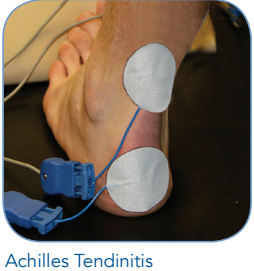
Ankles & Feet

Neuroma Pain or
Metatarsal Joint Pain

Ankle or Foot Pain
in Two Locations

Ankle or Foot Sprain

Ankles & Feet



Achilles Tendinitis

Plantar Fasciitis

WARNING: Electrodes must not touch each other.
See back cover for electrode description.

biowave

Manufactured by
Biowave Corporation
Norwalk, CT

MADE IN
USA

Device must only be used with power supply provided.

See User's Manual for more information.

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