

# deepwave®

Percutaneous Neuromodulation  
Pain Therapy System



# The Future of Pain Relief Has Arrived.

The Deepwave® Percutaneous Neuromodulation Pain Therapy System is a first course foundation therapy for treating chronic, acute or post-surgical musculoskeletal pain.

Deepwave® is an office-based procedure used under the supervision of a physician to break the pain cycle over four to six 30-minute treatments. Each treatment is typically separated by

48 hours. Deepwave® can be used to treat pain in numerous locations in the body including the lower back, cervical spine, hip, knee, ankle, foot, shoulder, elbow, wrist and hand.

## How is Deepwave® Superior to TENS?

### Patented Percutaneous Electrode Array

Deepwave® utilizes a patented microneedle patch electrode called a percutaneous electrode array or "PEA" that facilitates the delivery of therapeutic electrical energy through the skin directly into deep tissue encompassing the pain site. PEAs are sterile, single-use disposable electrodes comprised of over 1000 microneedles that are 0.74 millimeters in length and set within a 2.5-inch diameter patch. PEAs are comfortable and feel like sand paper or Velcro to the touch.

### Patented Advanced Electrical Signal Technology

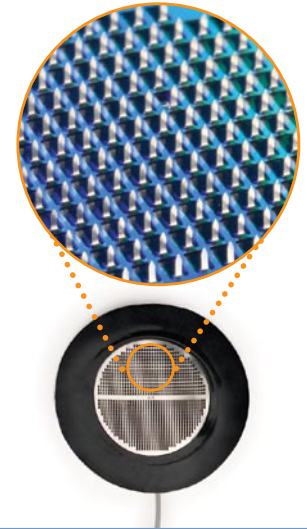
Deepwave® delivers a patented proprietary electrical signal technology into the body, which differs from other electrical stimulation modalities as follows:

First, low frequency signals (1-180Hz in frequency) are required to affect pain fibers in the body. However electrical signals in this frequency range cannot pass through the skin because of the skin's impedance and capacitance. TENS devices try to deliver low frequency signals between 2 or 4 electrodes. The effect is a "busy bees" sensation on the skin in between the electrodes. TENS may

act as a distraction to the pain while the device is on (this is known as Gate Control Theory), however there is little residual benefit and no functional improvement following the treatment.

In developing Biowave's technology, we knew that high frequency signals (greater than 1000Hz in frequency) can easily pass through the skin, but individually, such signals do not affect pain fibers.

Biowave discovered and patented that when 2 or more high frequency signals are combined together in our device and then delivered into the body through a single electrode, the signals will pass into deep tissue in the body to a second opposing electrode. As the combined high frequency signals pass through the body, polarized structures like the membrane of the C-fiber and muscle tissue force these signals to further multiply together resulting in a new spectrum of signals in the body. One of the new signals formed in deep tissue inside the body is a low frequency signal that inhibits the transmission of pain signals along pain fibers. Additionally, muscle tissue is held in contraction in the region of the electric field which may relate to the increased functional outcomes reported by patients and in clinical trials.



### PATENTED PAIN BLOCKING TECHNOLOGY.

The Deepwave® system uses a patented percutaneous electrode array (PEA) to facilitate delivery of therapeutic energy through the skin, into deep tissue. The therapeutic energy encompasses the pain site and blocks the transmission of musculoskeletal pain.

### Superior Clinical Outcomes

Published randomized, controlled clinical studies showing significant pain reduction, functional improvement and a reduction in pain medication consumption have been completed at several prestigious institutions including:

- Hospital for Special Surgery, New York, NY
- Rush University Medical Center, Chicago, IL
- Weill Medical College at Cornell University/NY Hospital, New York, NY

*Clinical studies are available upon request.*

## Targeting of Electric Field and Electrode Placement Rationale

Deepwave® uses either two PEAs to treat two distinct volumes of tissue, or pairs one PEA with one non-invasive electrode to target and focus most of the signals directly beneath the PEA. The PEA is placed directly over the center of the painful area or over the source of the pain. The non-invasive electrode is placed over a secondary point of pain or in an opposing location. This placement is necessary because the mixing of the high frequency signals from the device are concentrated in a 2"–3" volume of tissue beneath both electrodes—not along the surface of the skin between electrodes.

By pairing a PEA with both a non-invasive and larger area electrode, the low frequency field created by the body is concentrated beneath the PEA in a volume of tissue that encompasses the pain site.

With TENS, the signal travels along the surface of the skin between 2 or 4 electrodes and the effect occurs on the surface between the electrodes, not underneath each electrode, so it is difficult to target the pain site.

In Biowave's first dosage study conducted at Weill Medical College of Cornell University/New York Hospital, we determined there are an optimal set of high frequency signals for delivering energy into the body and an optimal low frequency signal that forms in deep tissue for inhibiting pain transmission and improving function. This resulted in the design of a very simple to use device that is purposely not programmable and from which an optimized set of signals are delivered into deep tissue.

## Empirical Results Unique to Deepwave®

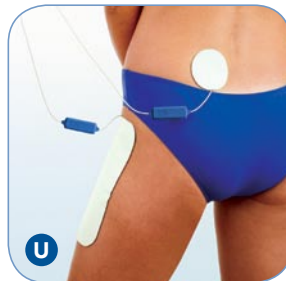
Empirical results produced by Deepwave® which are not generated by conventional electrical stimulation devices include:

- Long carryover effect following a 30-minute treatment—up to 24 hours of continued pain relief and functional improvement;
- Paresthesia at the location of the pain site electrode;
- Muscle in the region of the low frequency electric field is held in contraction during the course of the treatment; there is typically no muscle fasciculation or twitching.

## SAMPLE ELECTRODE PLACEMENTS

Deepwave® Percutaneous Electrode Array (PEA) placements are different from conventional electrical stimulation. The mixing of the proprietary therapeutic signals occurs in a 2"–3" volume of tissue beneath each electrode, not along the surface of the skin between the electrodes.

As a result, the PEA electrode is placed directly over the pain site. The larger rectangular electrode is placed over a secondary point of pain or in an opposing location. In some cases, 2 PEA electrodes may be used for bilateral pain where each electrode is placed directly over a painful area.



U Low Back Pain in One Location



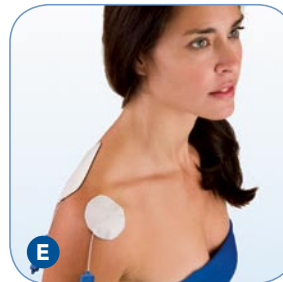
B Bilateral Low Back Pain



E Lateral or Medial Knee Pain



E Patellar Tendinitis



E Front or Top of Shoulder Pain



E Cervical Pain in One Location or Back of Shoulder Pain



E Wrist, Hand or Finger Pain




E Lateral or Medial Epicondylitis



E Foot or Ankle Pain

B Bilateral E Extremities U Unilateral

See back cover for electrode descriptions.

PRODUCT SPECIFICATIONS	ORDERING INFORMATION																								
<p><b>Physical Dimensions</b></p> <p><b>Size (H x W x D):</b> 8.80" x 6.31" x 3.07" / 22.35 cm x 16.02 cm x 7.79 cm</p> <p><b>Weight:</b> 2.9 lbs / 1.3 kg</p> <p><b>Environmental Conditions</b></p> <p><b>Operating Temperature:</b> 0 – 40 °C / 32 – 104 °F</p> <p><b>Humidity:</b> 30 – 85% relative humidity, non-condensing</p> <p><b>Signal Output</b></p> <p><b>Feed Frequency 1:</b> 3858 Hz</p> <p><b>Feed Frequency 2:</b> 3980 Hz</p> <p><b>Output Voltage Range:</b> 0 – 27.5 V rms</p> <p><b>Waveform:</b> Sum of 2 sine waves</p> <p><b>Power Source</b></p> <p>12 V DC, 3850 mAh rechargeable NiMH battery</p> <p>Provides 8 hours of power at 80% output into 500 Ohms</p> <p><b>Leadwire</b></p> <p>Rating complies with 21 CFR Part 898 (performance standards for electrode leadwires)</p> <p><b>Percutaneous Electrode Array (PEA)</b></p> <p>1.5" diameter microneedle array within 2.5" diameter hydrogel-based sterile electrode</p> <p>1014 microneedles made from 316L surgical stainless steel</p> <p><b>Length:</b> 0.74 mm</p>	<table border="0"> <thead> <tr> <th data-bbox="841 365 899 390">Item</th> <th data-bbox="976 365 1110 390">Description</th> </tr> </thead> <tbody> <tr> <td data-bbox="841 411 943 436">DWD001</td> <td data-bbox="976 411 1182 436">Deepwave® Device</td> </tr> <tr> <td data-bbox="841 468 943 531">DWE001 ⓑ</td> <td data-bbox="976 468 1451 562">Two 2.5" diameter Percutaneous Electrode Arrays for ⓑ bilateral low back, bilateral cervical and knee electrode placements.</td> </tr> <tr> <td data-bbox="841 594 943 657">DWE002 ⓔ</td> <td data-bbox="976 594 1468 720">One 2.5" diameter Percutaneous Electrode Array with one 2" x 4" Small Feed Electrode for use on ⓔ extremities such as the knee, ankle, foot, shoulder, elbow, wrist and hand.</td> </tr> <tr> <td data-bbox="841 751 943 814">DWE003 Ⓤ</td> <td data-bbox="976 751 1459 919">One 2.5" diameter Percutaneous Electrode Array with one 5" x 8" Large Feed Electrode for Ⓤ unilateral low back, buttock, hip, quadricep and hamstring electrode placements.</td> </tr> <tr> <td data-bbox="841 951 943 976">DWL001</td> <td data-bbox="976 951 1122 976">Leadwire Set</td> </tr> <tr> <td data-bbox="841 1008 943 1033">DWB001</td> <td data-bbox="976 1008 1057 1033">Battery</td> </tr> <tr> <td data-bbox="841 1064 943 1089">DWA001</td> <td data-bbox="976 1064 1349 1089">AC Adapter and Power Cord - US</td> </tr> <tr> <td data-bbox="841 1121 943 1146">DWU001</td> <td data-bbox="976 1121 1357 1146">Deepwave® User's Manual (English)</td> </tr> <tr> <td data-bbox="841 1178 943 1203">DWQ001</td> <td data-bbox="976 1178 1349 1203">Deepwave® Quick Reference Card</td> </tr> <tr> <td data-bbox="841 1234 943 1260">DWPB01</td> <td data-bbox="976 1234 1289 1260">Deepwave® Patient Brochure</td> </tr> <tr> <td data-bbox="841 1291 943 1316">DWBH01</td> <td data-bbox="976 1291 1373 1316">Deepwave® Patient Brochure Holder</td> </tr> </tbody> </table> <p><b>biowave</b> </p> <p>Manufactured by Biowave Corporation 16 Knight Street Norwalk, CT 06851</p> <p>T: 1-877-BIOWAVE E: info@biowave.com W: www.biowave.com ©2008 Biowave Corporation</p>	Item	Description	DWD001	Deepwave® Device	DWE001 ⓑ	Two 2.5" diameter Percutaneous Electrode Arrays for ⓑ bilateral low back, bilateral cervical and knee electrode placements.	DWE002 ⓔ	One 2.5" diameter Percutaneous Electrode Array with one 2" x 4" Small Feed Electrode for use on ⓔ extremities such as the knee, ankle, foot, shoulder, elbow, wrist and hand.	DWE003 Ⓤ	One 2.5" diameter Percutaneous Electrode Array with one 5" x 8" Large Feed Electrode for Ⓤ unilateral low back, buttock, hip, quadricep and hamstring electrode placements.	DWL001	Leadwire Set	DWB001	Battery	DWA001	AC Adapter and Power Cord - US	DWU001	Deepwave® User's Manual (English)	DWQ001	Deepwave® Quick Reference Card	DWPB01	Deepwave® Patient Brochure	DWBH01	Deepwave® Patient Brochure Holder
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