BiowavePENS

Percutaneous Electrical Nerve Stimulation System

Training & Inservice

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Background on **Pain** For **Sales Representatives**

What is **Pain?**

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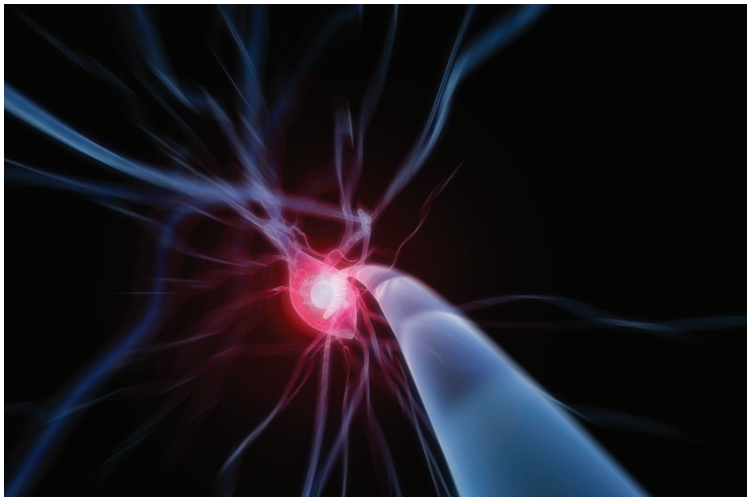
Pain is broadly divided into two groups: Nociceptive Pain and Neuropathic Pain



Nociceptive Pain

- Caused by intense or damaging stimuli
- Three classes of nociceptive pain:
  - Mechanical (stubbing a toe)
  - Thermal (burning a finger)
  - Chemical (putting alcohol on a cut)
- Examples include:
  - Post–operative pain
  - Pain associated with trauma
  - Chronic pain of arthritis

Neuropathic Pain

- Caused by nerve damage accompanied by tissue injury
- Damaged nerve fibers send incorrect signals to different pain centers
- Examples include:
  - Allodynia
  - Radiculopathies
  - Neuralgia
  - Postherpetic neuralgia (shingles)
  - Complex Regional Pain Syndrome (CRPS)
  - Phantom limb pain

Types of Pain Fibers

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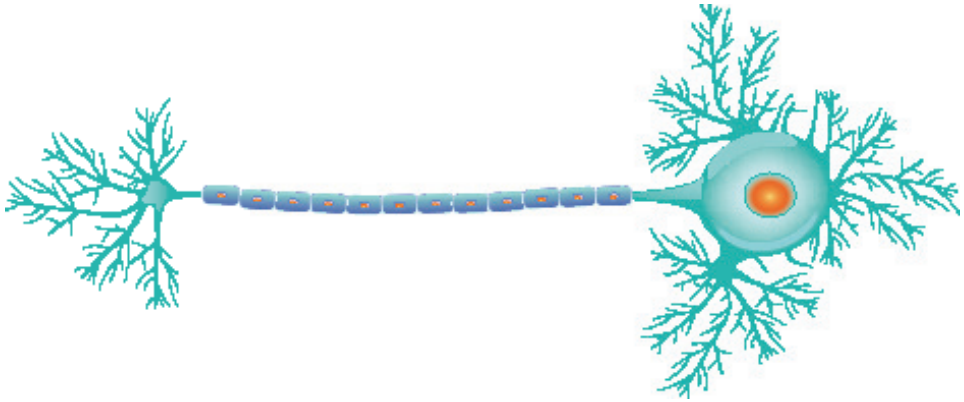
Nociceptors can be divided into two general types.



C-fibers

- Unmyelinated axons
- Conduct action potentials slowly
- Small-diameter cell bodies
- Mediate the slower, burning quality of pain
- Comprise around 70% of all nociceptor fibers

A-delta fibers

- Lightly myelinated axons
- Conduct action potentials rapidly
- Medium to large diameter cell bodies
- Mediate the fast, pricking quality of pain fibers

Acute vs. Chronic

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Acute pain and chronic pain differ in their time frame, etiology, pathophysiology, diagnosis and treatment.

Acute pain

- Less than 3-months in duration
- Results from trauma or postoperative pain
- Self–limiting and serves as a protective biological function by acting as a warning of ongoing tissue damage
- Symptom of a disease process experienced in or around the injured or diseased tissue
- Nociceptive in nature and occurs secondary to chemical, mechanical and thermal stimulation of A–delta and C–fiber pain receptors.

Chronic pain

- Greater than 3-months in duration
- Serves no protective biological function
- Chronic pain is itself a disease process
- Not self– limiting and can persist for years and even decades after the initial injury
- Can be refractory to multiple treatment modalities
- If inadequately treated, associated symptoms can include chronic anxiety, fear, depression, sleeplessness and impairment of social interaction predominately neuropathic in nature (except for cancer pain) and involves damage either to the peripheral or central nervous systems

How is **Pain Transmitted?**

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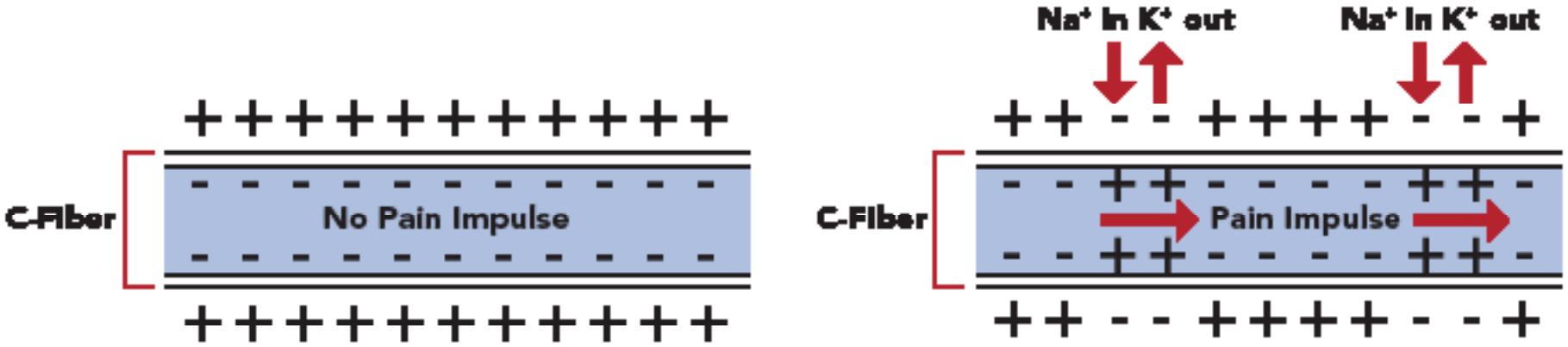
Pain is initiated by an external stimulus that exceeds a certain threshold.



- Stimulus from outside the body is above a certain threshold (for example, a person hits their thumb with a hammer)
- Sodium ion passes from the outside of the membrane of the C- fiber to the inside of the C-fiber
- Potassium ion moves from the inside of the C-fiber to the outside
- Sodium-potassium ion exchange causes a polarity change
- Plus charge formed on the inside of the C- fiber is the pain signal
- Pain signal propagates along C- fiber to dorsal horn of the spine and up to the brain
- Person feels pain

Different Ways to Treat Pain

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Tier 1

TENS
Electrical signals travel across surface of skin which may act as a distraction to pain

Gate Control Theory

NSAIDS
Reduces inflamation through peripheral inhibition of prostaglandin synthesis

Bio-feedback
Provides some control over physiological functions

Physical Therapy
Strengthens location surrounding injured area

Behavioral Modification
Reduces re-aggravation of pain condition

Tier 2

Opioids
Act on receptors located on neuronal cell membranes that inhibit neurotransmitter release

Nerve Blocks
Provides a chemical conduction block of the sodium channels which conduct electrical pain impulses

Injections
Suppresses the immune system reducing inflammation, pain and swelling at the site of the injury

Radio Frequency Ablation
Burns nerves to stop transmission of pain signals

Tier 3

Surgery
Mechanical correction or stabilization to reduce pain

SCS
Implanted device and leads stimulates affected nerves

Gate Control Theory

Drug Pumps
Provides a chemical conduction block of the sodium channels which conduct electrical pain impulses

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Clinical and Technical
Inservice on Biowave

Problem with Existing Stimulation Technologies

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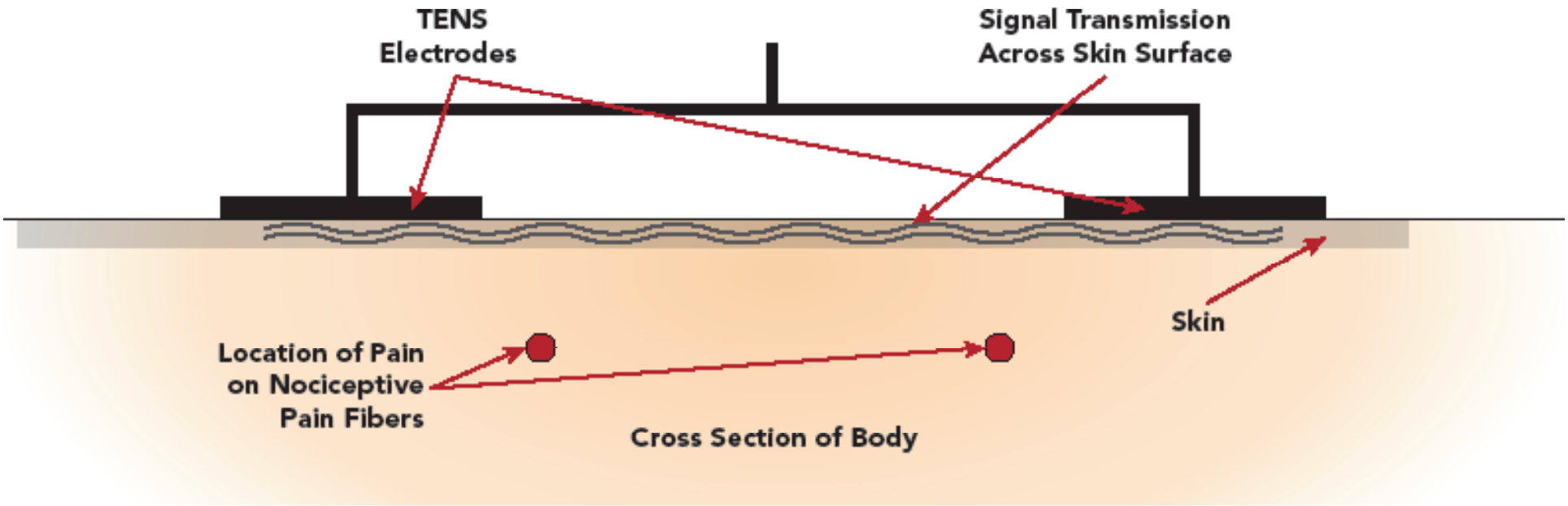

- Low Frequency signals (1-180 hz) affect nerve fibers
- Problem - skin has high impedance & capacitance
- Low Frequency (LF) signals regardless of the shape of the waveform cannot pass through skin - LF signals only travel across the surface of skin (Fundamental problem with TENS)
- PNS and SCS devices are implanted with leads placed in the proximity of the nerve to be stimulated

First Solution to Problem

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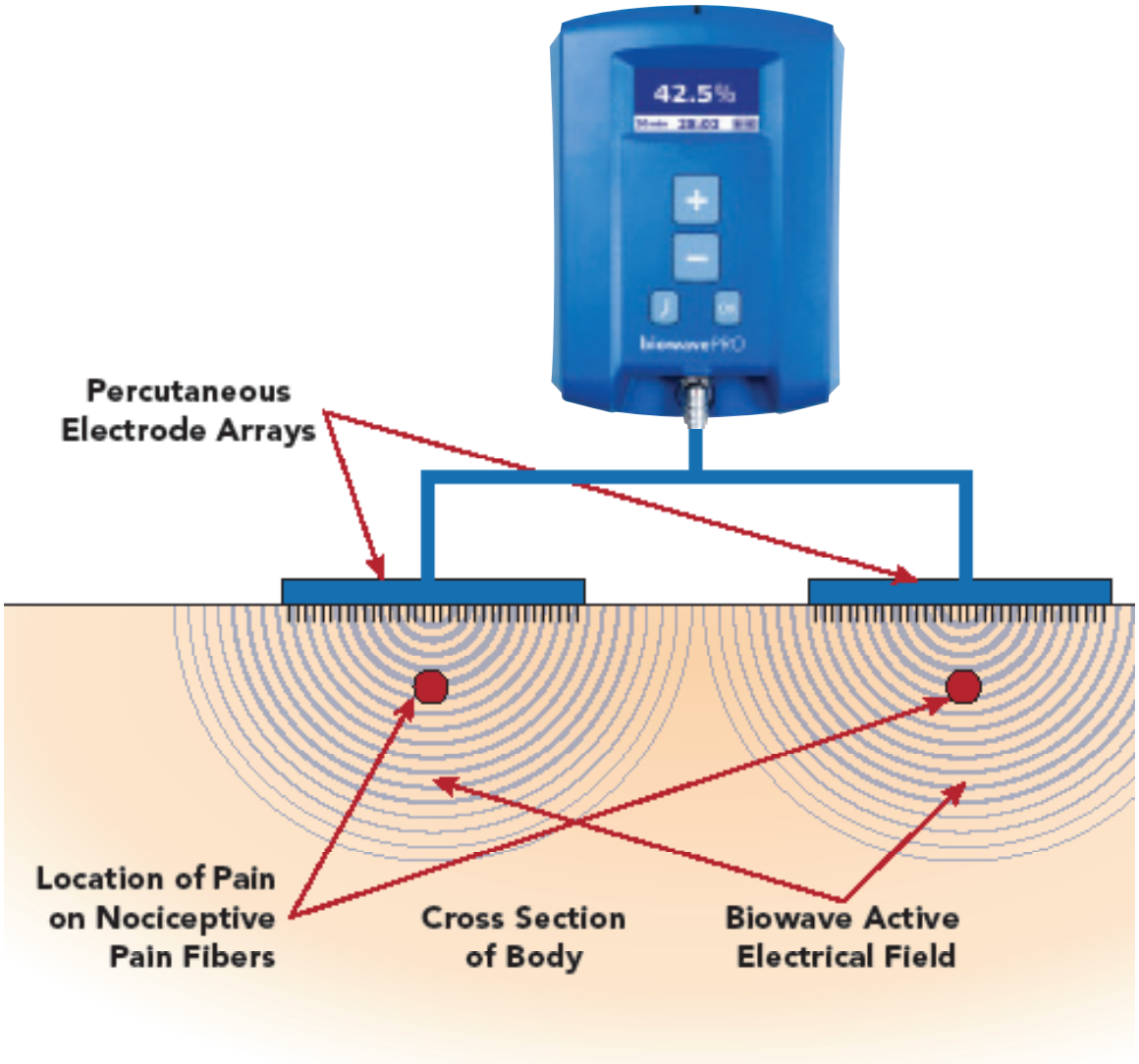
Patented Biowave Advanced Signal Technology



- Proven in a rabbit model
- Delivery of Biowave's two summed High Frequency (HF) signals (4000 hz + 3880 hz) alternates between two percutaneous electrodes
- As the 2 HF signals pass through skin into deep tissue, all polarized structures including nociceptive pain fibers (C-fiber, A-delta fiber) and muscle tissue cause a further multiplication of the 2 HF signals (this is known as a Fourier Transform)
- Result is a new spectrum of signals, one of which is a Low Frequency (LF) signal that forms an active electrical field in a 3.5" diameter hemisphere beneath each percutaneous electrode
- Body is producing LF internally at surface of pain nerves instead of:

  1. trying to force LF through skin from the outside like TENS, or
  2. needing to implant a lead next to the nerve like a spinal cord stimulator (SCS) or peripheral nerve stimulator (PNS)

Mechanisms of Action

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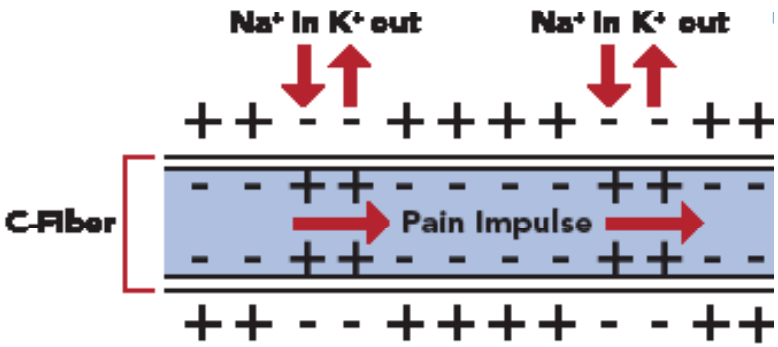
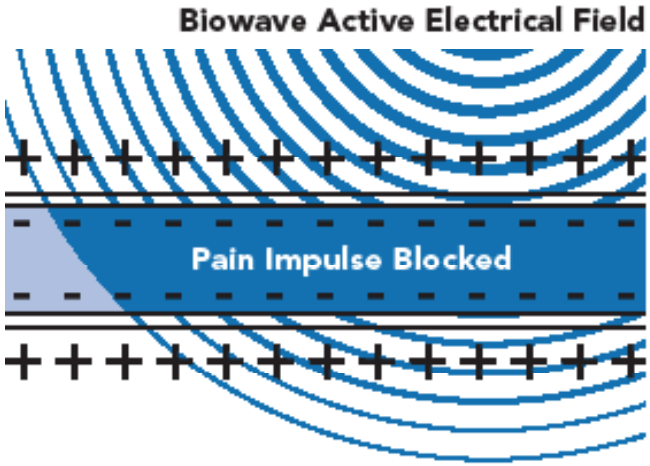
Biowave Treats Both Nociceptive and Neuropathic Pain

Before



After



- Active electrical field forms at the surface of nerves in a 3.5" diameter hemisphere beneath both electrodes
- Hyperpolarization of C Fibers
  - Active electrical field inhibits sodium – potassium ion exchange across the membrane of C-fibers preventing action potential propagation
- Hypoesthesia is induced on A-delta Fibers:
  - Hypoesthesia is induced 5 min into the treatment
  - Light numbness lasts for up to 20 min following a 30-min treatment
- Blood flow is accelerated through volume of tissue in hemisphere where active electrical field is present
- Muscle tissue held in tension during treatment
- Deep smooth pressure sensation – Much more comfortable than IFC, NMES, TENS
- Long carry over effect from more efficient production of endogenous opiates – endorphins, enkephalins, serotonin

Second Solution to Problem

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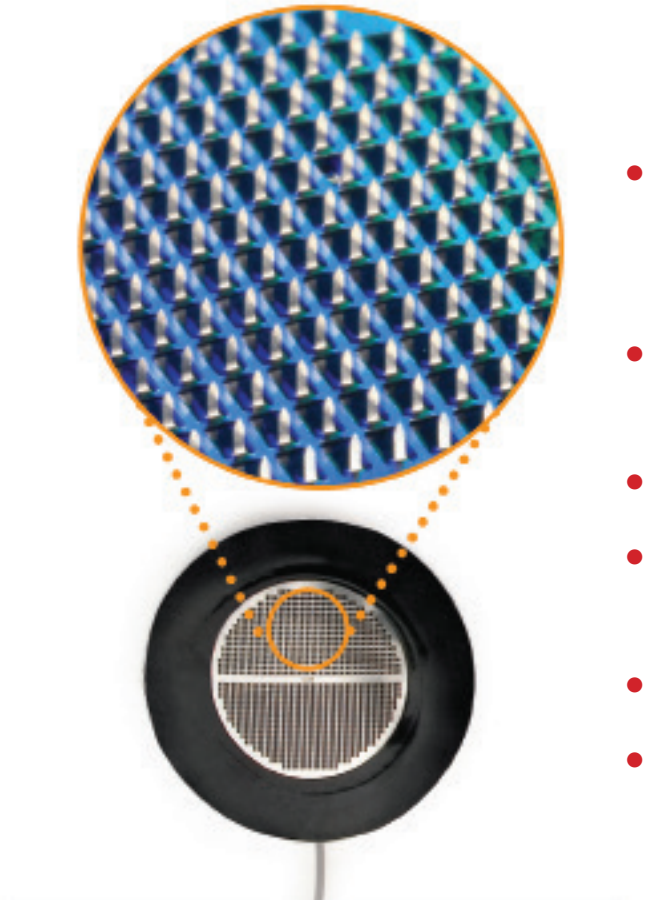
Patented Biowave Percutaneous Electrode



Biowave Precutaneous Electrode

- Percutaneous Electrode further facilitates delivery of therapeutic signals into deep tissue
- Percutaneous Electrode bypasses the impedance and capacitance of skin
- Sterile, Single-Use
- 2.5" diameter electrode, 1014 needles, 0.74mm in length
- Feels like Velcro to the touch
- Allows for 3.5" diameter hemisphere treatment area

Electro-acupuncture vs. PENS

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Electro-acupuncture	Conventional PENS
1 – 10, 3" long needles	1 – 10, 3" long needles
Needles are inserted along meridians in body based on Eastern Medicine	Needles are inserted near the nerve where pain signals are conducted
No imaging used to guide needle placement	No imaging used to guide needle placement
Stimulation location is limited to tip of needle	Stimulation location is limited to tip of needle
30 – 40% response rate	30 – 40% response rate

Conventional PENS vs. BiowavePENS

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Conventional PENS	BiowavePENS
1 – 10, 3" long needles	2, 2.5" diameter arrays of 1014 needles
2.0 cm^2 of needle surface area through skin (10 needles)	3.3 cm^2 of needle surface area through skin
Needles are inserted near nerves conducting pain signals	Needle Array is inserted directly over nerves conducting pain
Stimulation location is limited to tip of needle	Stimulation location = 3.5" diameter hemisphere beneath each needle array
30 – 40% response rate	**75% response rate**

First **Human Study**

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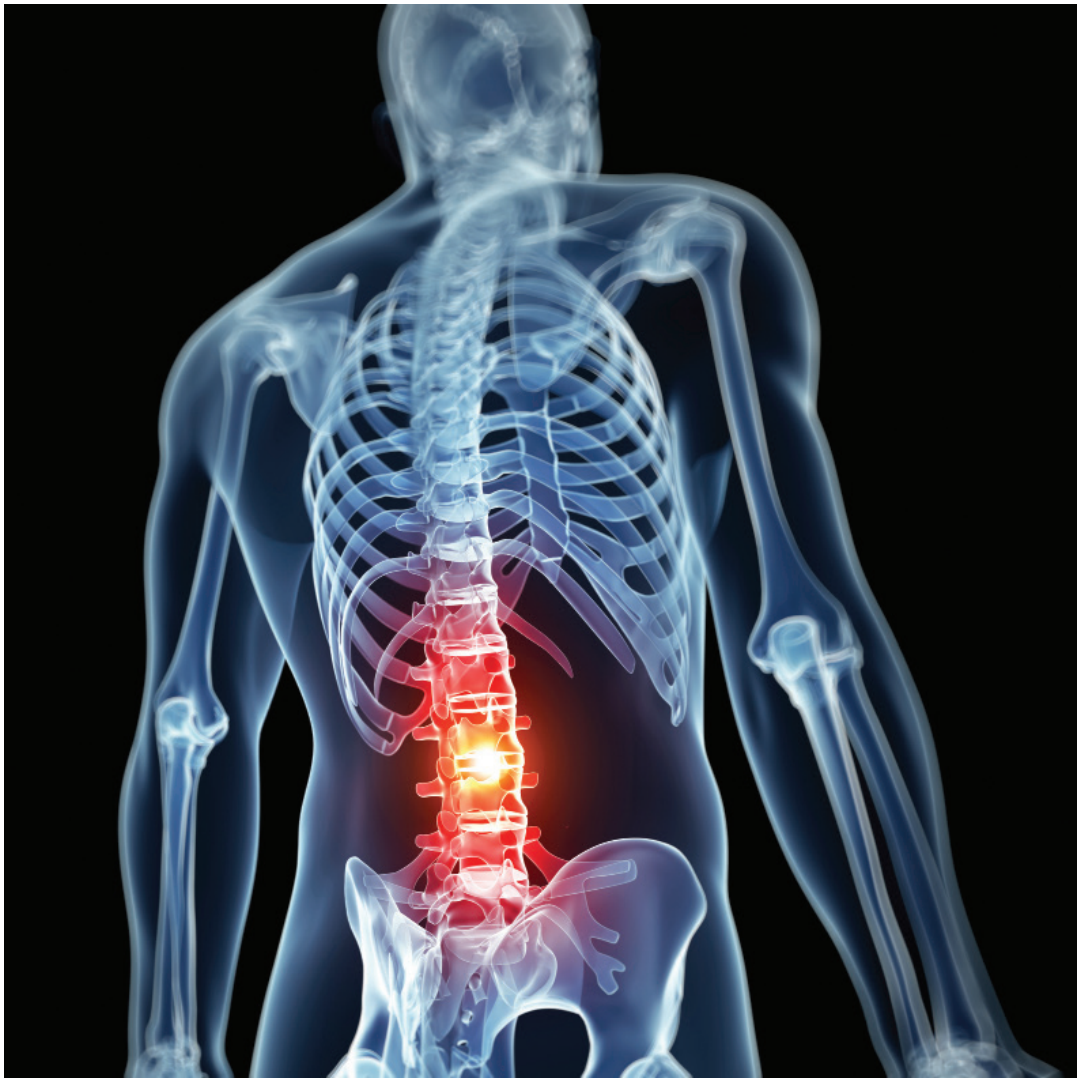
Chronic Low Back Pain Dosage Study at Cornell Medical College/NY Hospital



- Abstract in Journal Anesthesia & Analgesia Mar 2003
- Discovered optimal set of HF signals for passing energy through skin
- Discovered optimal LF signal formed inside body for:
  - preventing action potential propagation along C-fibers (inhibiting transmission of pain signal)
  - inducing hypoesthesia on A-delta fibers – light numbness forms in the hemisphere beneath and surrounding each electrode

Result

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Very Simple to Use Neuromodulation Pain Therapy System

- No programming
- Signals are optimized for passing through skin and blocking pain directly on nociceptive fibers
- Only control is intensity
- Patients control their own comfort level
- Active feedback control prevents patients from receiving a burn
- Very simple to use

Biowave **Clinical Studies**

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Clinical studies on acute, chronic and postoperative pain

- Randomized Controlled Study on the treatment of post-operative pain from TKA surgery - Hospital for Special Surgery, New York City - Podium Presentation at Eastern Orthopedic Association Annual Meeting, Oct 2008; Poster Presentation at AAOS Annual Meeting Feb 2009; Study submitted to the *Journal of Arthroplasty*
- Randomized Blinded Controlled Study Treating OA Knee Patients Rush Univ. Medical Center - Published in *ORTHOPEDICS* June 2007
- Weill Cornell Medical College Chronic Low Back Pain Study (Phase 1 + 2) - Abstract from *Anesthesia & Analgesia*, Mar 2003
- NY Giants White Paper - IRB approved study on treatment of Acute Sports Injuries on NY Giants football players June 2003-Dec 2005, 600 treatments on 90 players
- Clinical Study on treating extremities to reduce pain and improve range of motion - August 2005

Go to biowave.com/clinical to download studies

Biowave **Clinical Studies**

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Results from Clinical Studies

- **Excellent treatment outcomes**
  - 75% patient response rate
  - 50%-75% reduction in VAS pain scores
  - Significant increase in ROM, reduction in stiffness and muscle spasm
- **Long carry over effect**
  - 30-minute treatment provides up to 72 hours of continued pain relief and functional improvement
- **Extremely comfortable**
  - Deep smooth pressure sensation
  - Excellent patient compliance

Treatment **Regimen**

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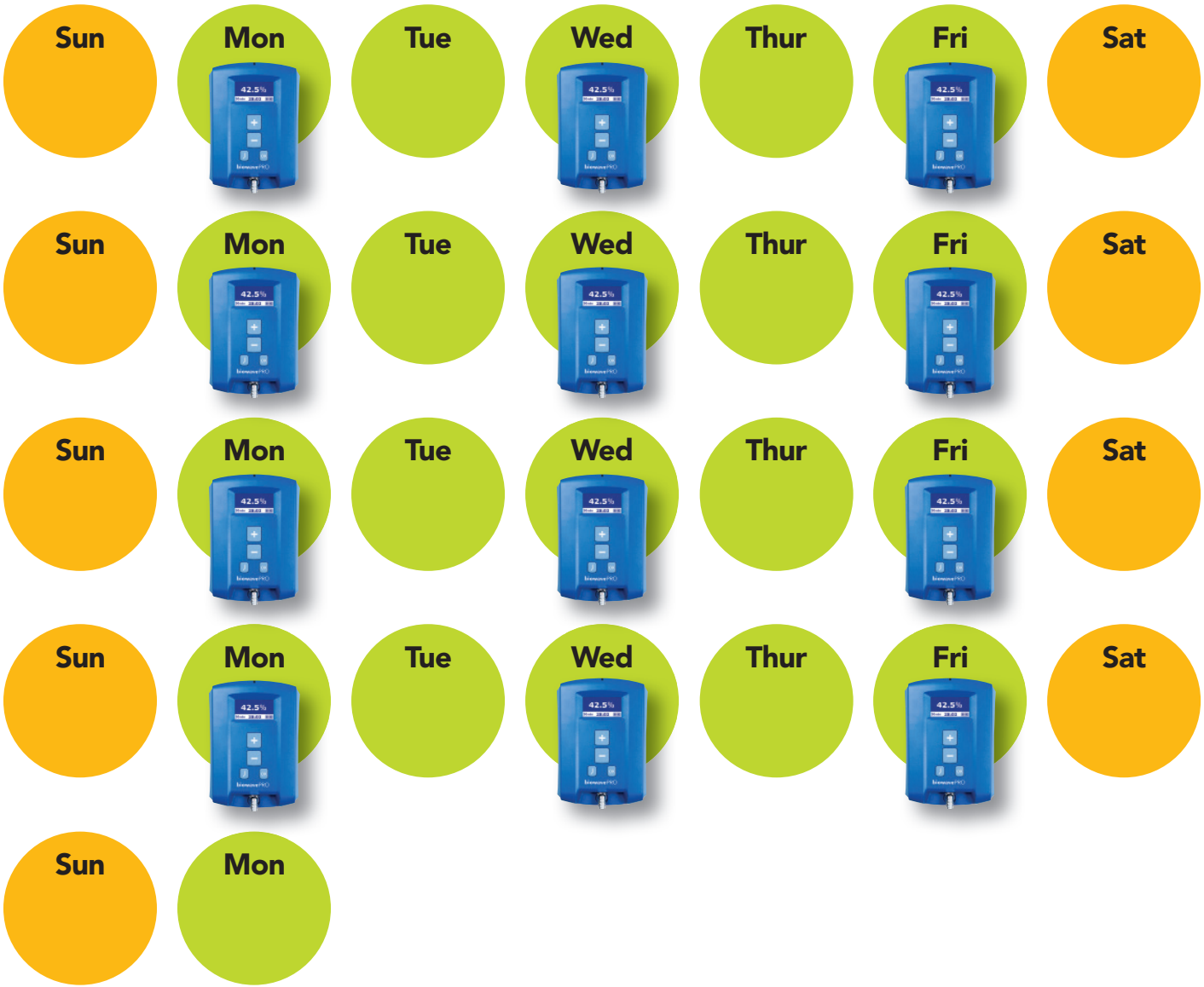
3X per week



- Pain or Spine Clinic
- Static Treatment (no activity during treatment)
- 12 treatments over 30 days
- Doctors and patients report cumulative benefits with multiple treatments

Treatment **Regimen**

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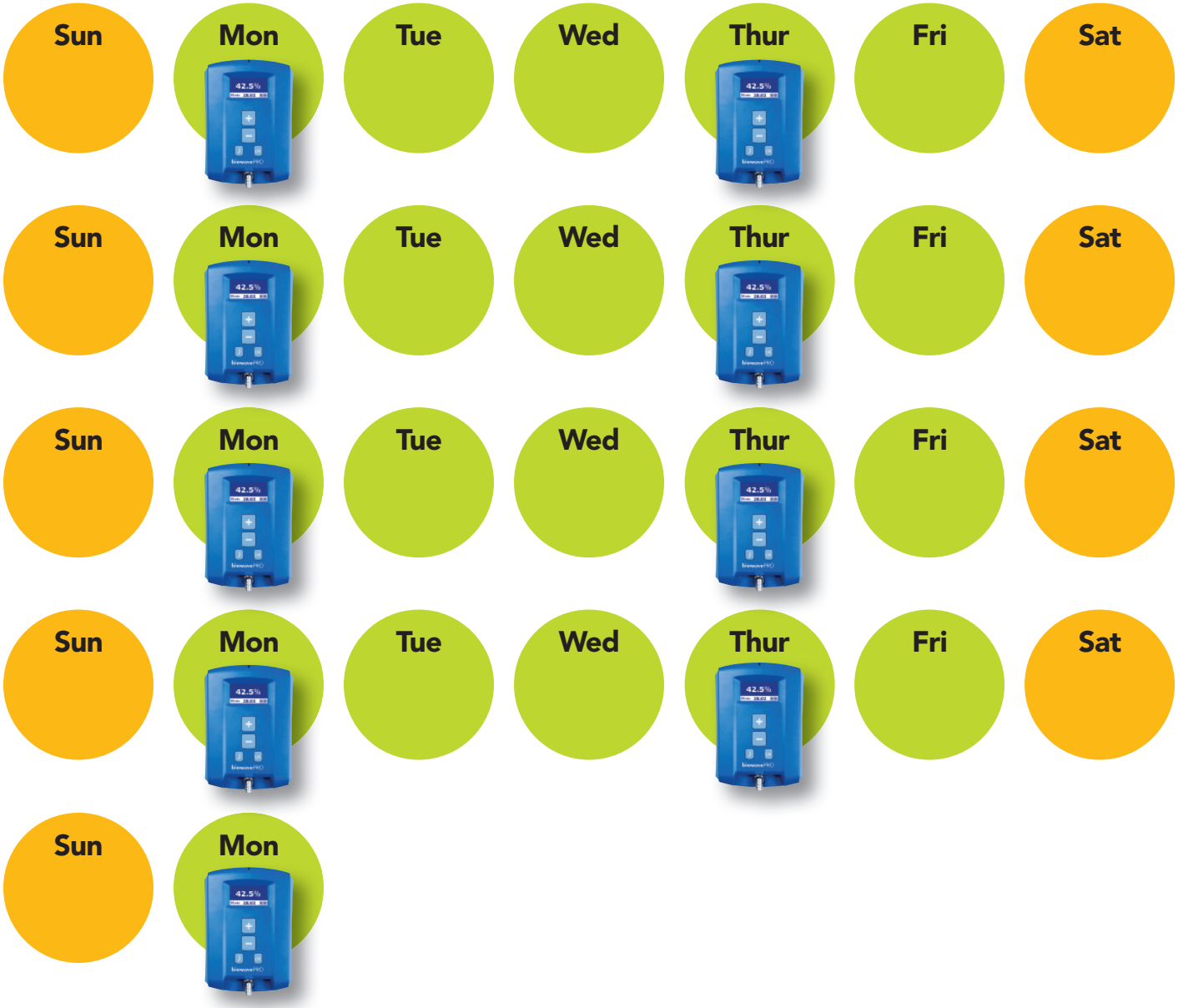
2X per week



- Pain or Spine Clinic
- Static Treatment (no activity during treatment)
- Up to 12 treatments over 30 days
- Doctors and patients report cumulative benefits with multiple treatments

Electrode Placement **Rationale**

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Electrodes must be placed directly over 2 locations of pain or over 1 pain site and over the origin of pain

B – Set Electrodes

- Two percutaneous electrodes, both of equal area
- Density of field is equal beneath both electrodes
- Impedance is equal and close to zero beneath both electrodes

Used for Treating:

- Two Locations of Pain
- One Pain Site & Origin of Pain
- One Large Area of Pain

Electrode **Placement Example**

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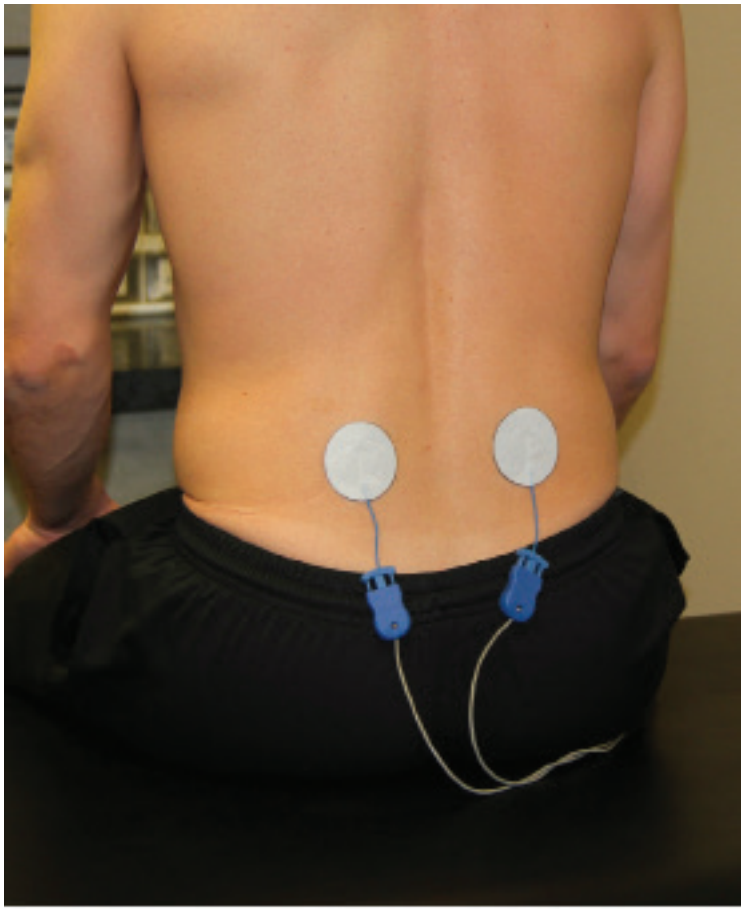
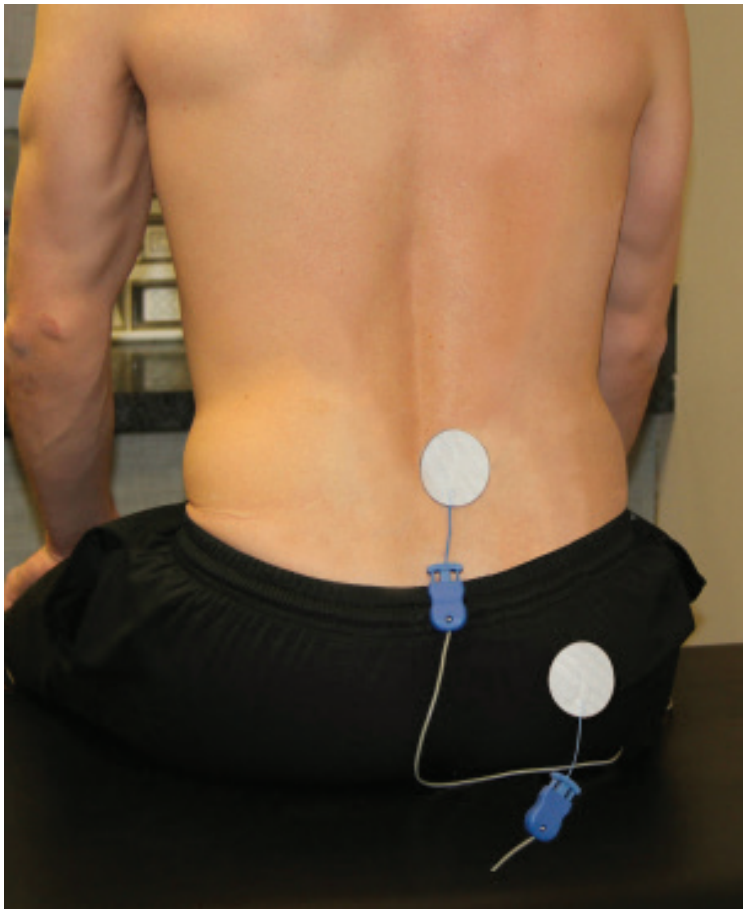
2 Locations of Pain or Radiculopathy



2 Locations of Pain
e.g. Bilateral Lumbar Pain



Origin of Pain and Most Proximal
Location of Pain e.g. Radiculopathy

Electrode **Placement Example**

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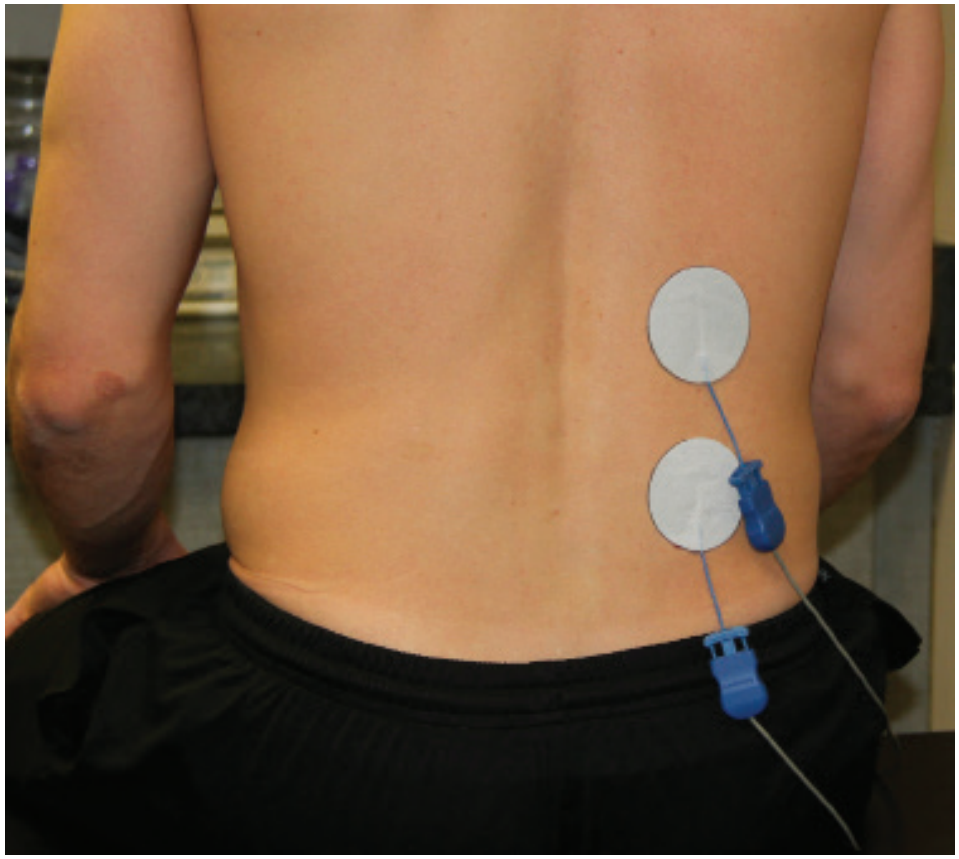
One Large Area of Pain



Treating One Large Area of Pain
e.g. Rotational Strain

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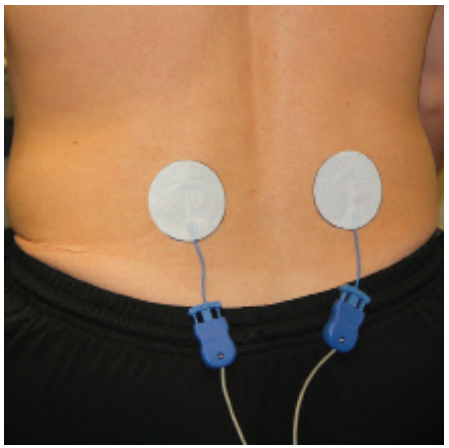
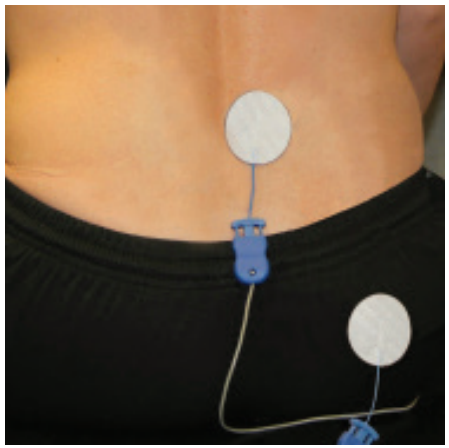
Percutaneous **Electrode Placement Examples**

Percutaneous **Electrode Placements**

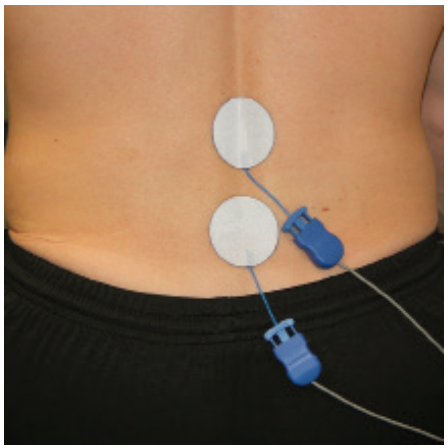
Lumbar Back



Bilateral Low Back Pain



Radiculopathy – Electrodes Over Source and Proximal Pain Site



Low Back Pain Focused Over One or Multiple Discs

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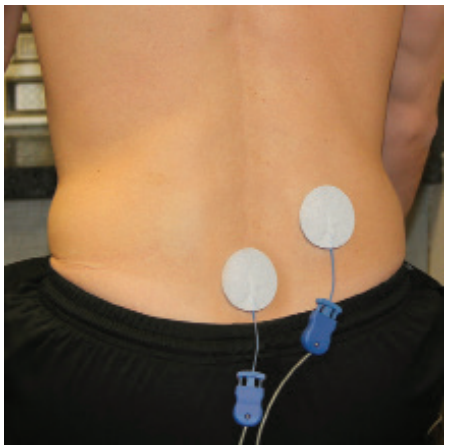
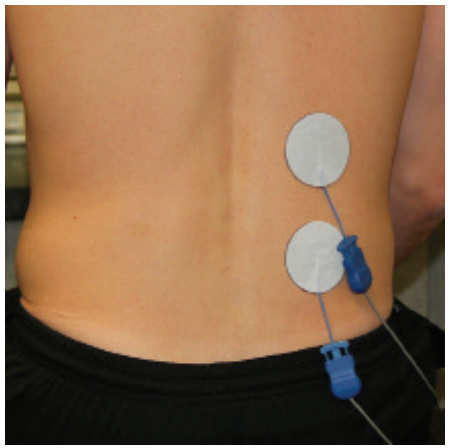
Percutaneous **Electrode Placements**

Lumbar/Hip

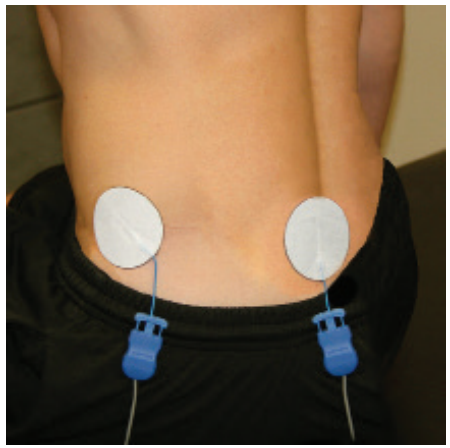


Unilateral Low Back Pain Focused on One Side of the Spine



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

Sacroiliac (SI) Joint Pain



Hip Pain

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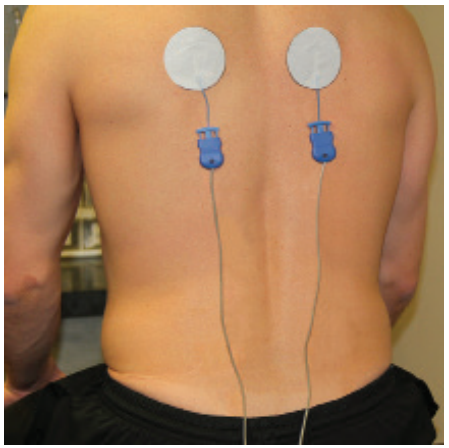
Percutaneous **Electrode Placements**

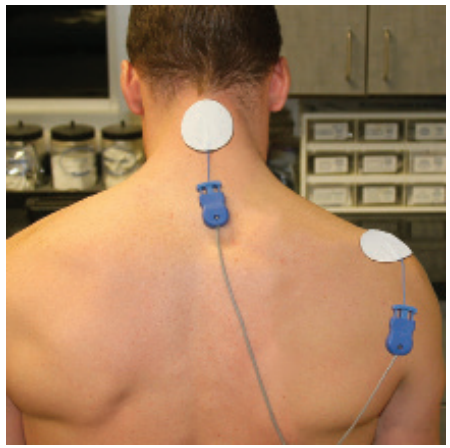
Thoracic/Cervical



Bilateral Thoracic Pain (Two Locations of Pain)

Cervical or Neck Pain

Cervical or Neck Pain in Two Locations



Radiculopathy – Electrodes Over Source and Proximal Pain Site

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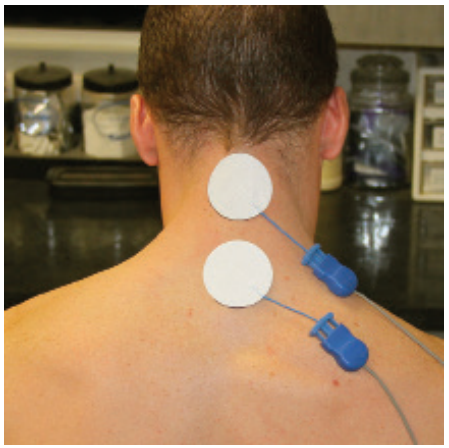
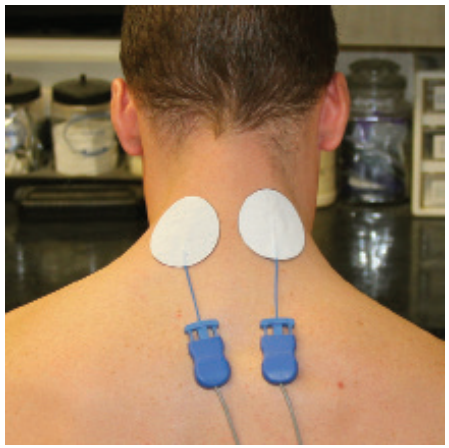
Percutaneous **Electrode Placements**

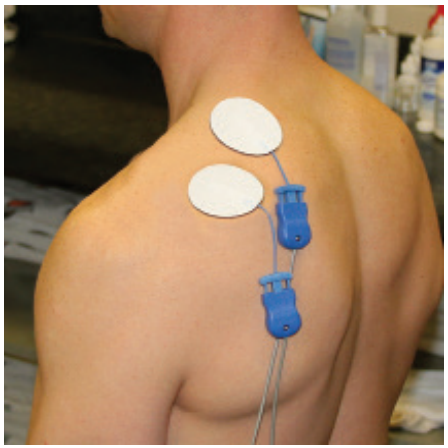
Cervical



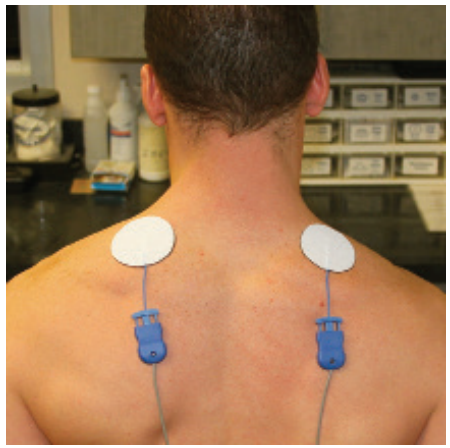
Neck Pain Over Several Cervical Discs



Bilateral Neck Pain (Two Locations of Pain)



Trapezius Pain (e.g. Trigger Point)



Bilateral Trapezius Pain (Two Locations of Pain)

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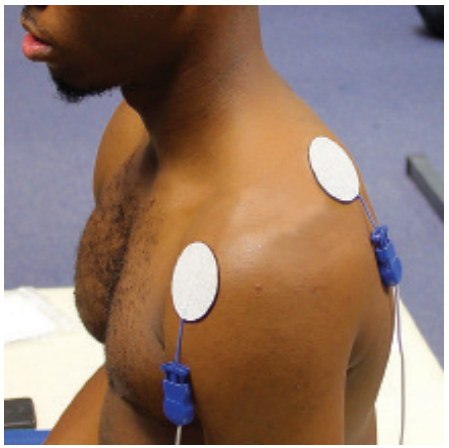
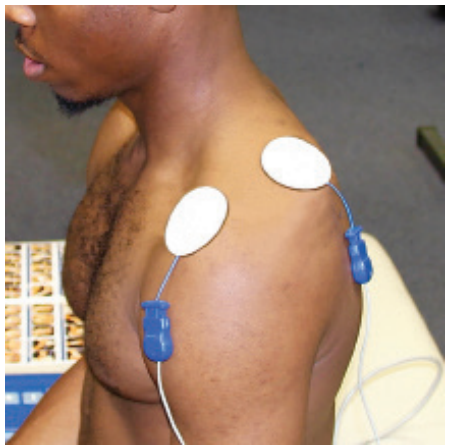
Percutaneous **Electrode Placements**

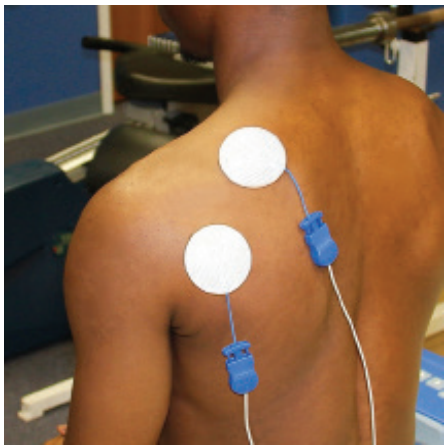
Shoulder



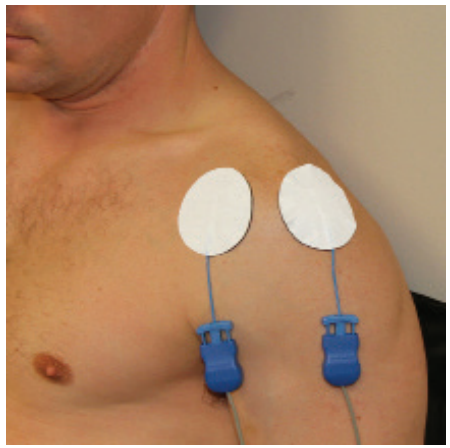
Anterior Shoulder Pain (e.g. Biceps Tendinitis)



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



Posterior Shoulder Pain (e.g. Infraspinatus Sprain, Posterior Rotator Cuff)



Shoulder Pain in Two Locations (e.g. General Post-op Shoulder Pain, SLAP Tear, Adhesive Capsulitis)

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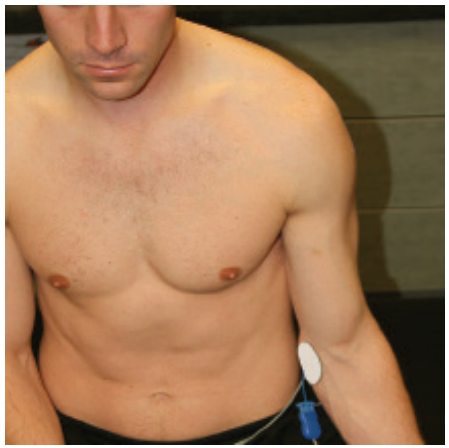
Percutaneous **Electrode Placements**

Elbows

Lateral Elbow Pain
(e.g. Lateral Epicondylitis)



Medial Elbow Pain
(e.g. Medial Epicondylitis)

Posterior Elbow Pain
(e.g. Triceps Tendinitis)

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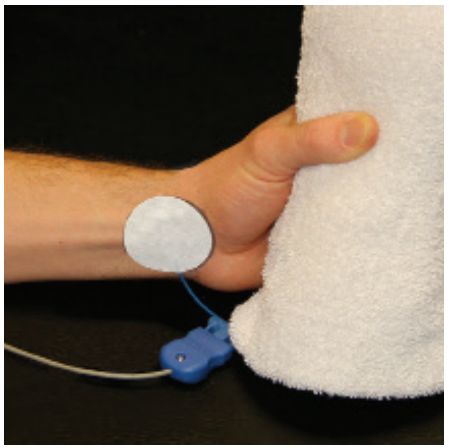
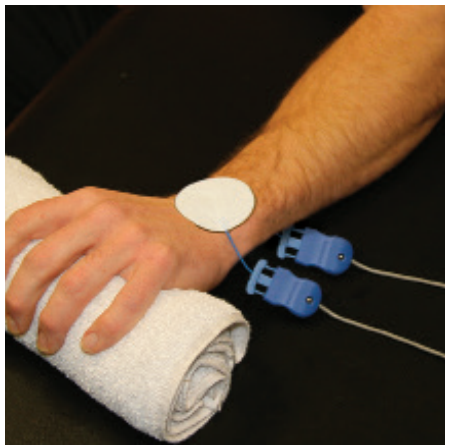
Percutaneous **Electrode Placements**

Wrist, Hands & Fingers



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



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

Pain at Metacarpal Phalangeal or Interphalangeal Joint

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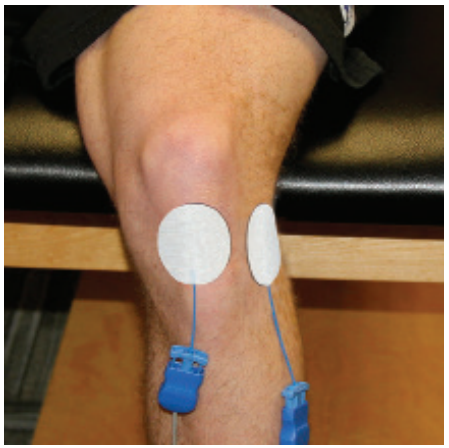
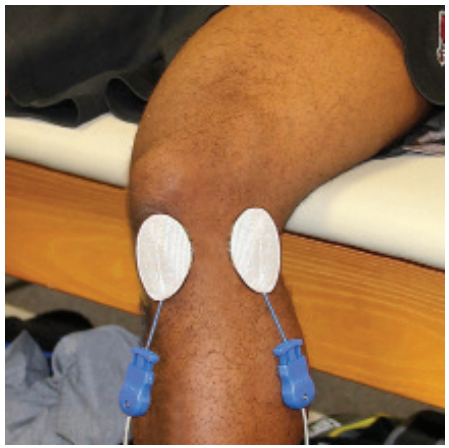
Percutaneous **Electrode Placements**

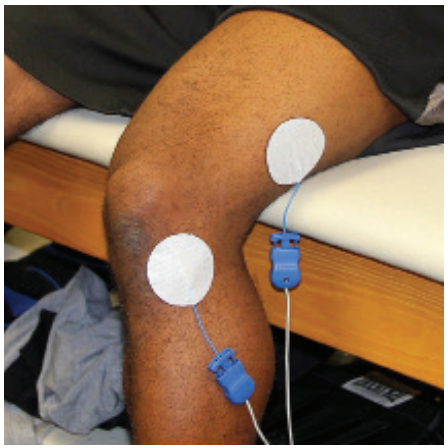
Knees



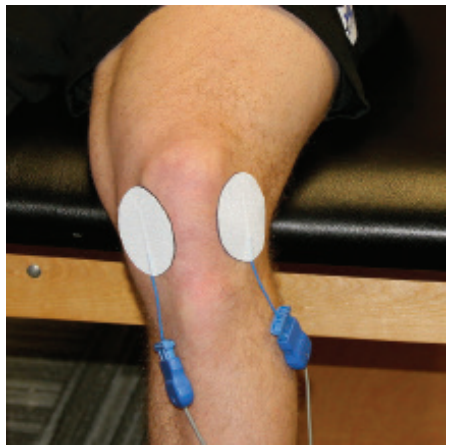
Patellar Tendinitis



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



Illiotibial (IT) Band Pain In Two Locations



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

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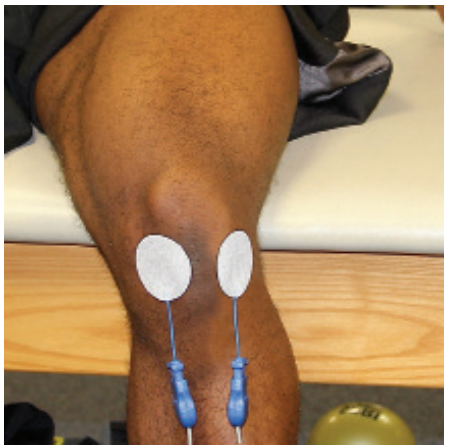
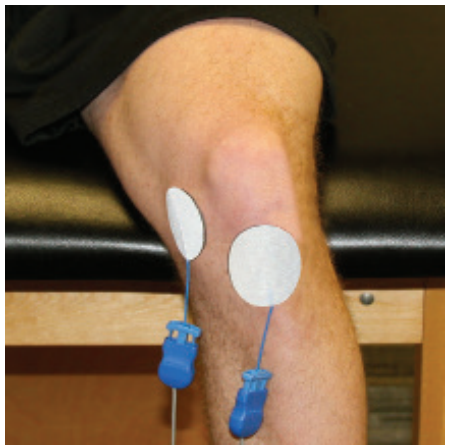
Percutaneous **Electrode Placements**

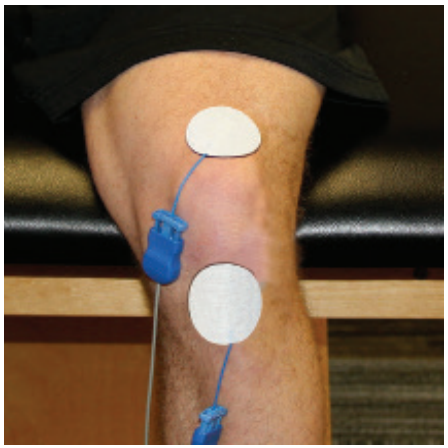
Knees



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



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



Quadriceps Tendinitis

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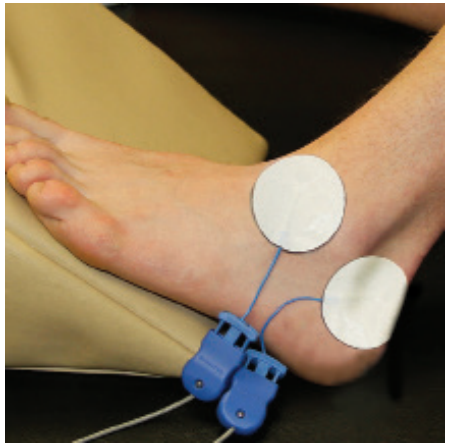
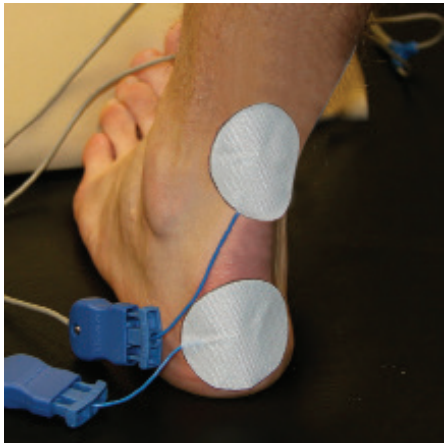
Percutaneous **Electrode Placements**

Ankles & Feet

Ankle or Foot Pain in Two Locations



Ankle or Foot Sprain



Achillies Tendinitis

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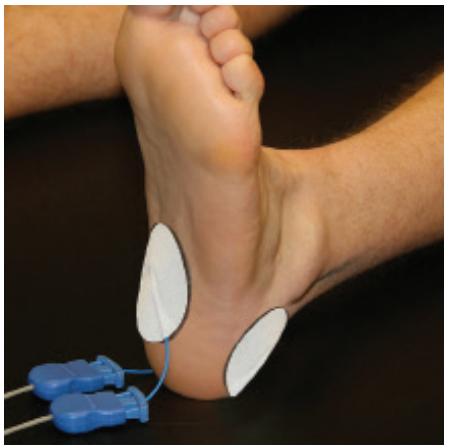
Percutaneous **Electrode Placements**

Ankles & Feet



Plantar Fasciitis

Neuroma Pain or Metatarsal Joint Pain

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Body Position During Treatment

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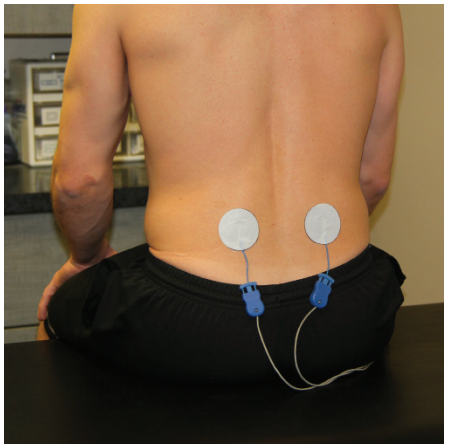
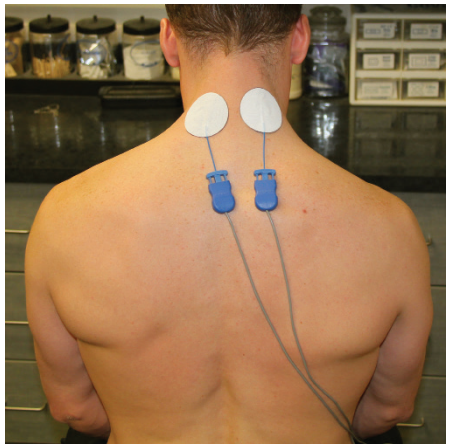
Tissue should be taut or in a stretch position

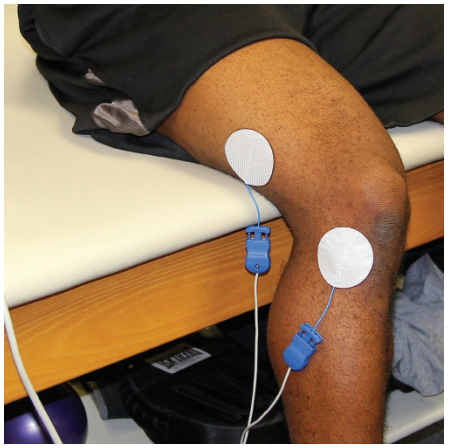
- **Lumbar** – torso at 90° to legs
- **Neck** – tilted forward
- **Knee** – bent at 90°
- **Shoulder** – neutral position



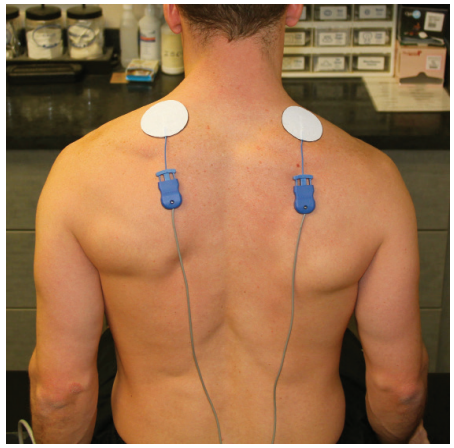
Lumbar Position



Neck Position



Knee Position



Shoulder Position

Motion During Treatment

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Motion can change location of the electrical field

Gently and slowly articulate the pain site location to find positioning that causes the *sensation* from the electrical field to encompass the location of pain

Treatment **Set Up**

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- Treatment must be performed under supervision of physician; May be performed by RN, PA, MA, PT, ATC
- Determine B or E set electrodes for pain condition
- Palpate to find center of pain location
- Mark skin with Sharpie for center of each electrode placement
- Clean skin with alcohol prep
- Insert percutaneous electrodes through skin; apply 10 lbs of force
- Connect leadwire cable to percutaneous electrodes and stimulator
- Turn stimulator on
- Stimulator may sit on counter or sideways on patient's lap so cable exits to the side
- Patient controls the intensity and their own comfort level by pressing the PLUS button
- No Programming
- Total set-up time is about 3 minutes

Operation of Device

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- Patient begins treatment by pressing PLUS button
- Intensity increases in 0.5% increments with each press of PLUS button
- Patient should advance intensity to tolerance so sensation felt is strong but still comfortable
- As body adapts to electrical field, sensation diminishes
  - Patient should continue to advance intensity to keep sensation strong during entire 30 minute treatment
  - As hypoestheisa develops in first 5 minutes, initial sharper sensation is masked and treatment becomes even more comfortable
- Most patients advance the intensity level to:
  - 10% - 15%, 5-10 minutes into the treatment
  - 20% - 30% by the end of the 30-minute treatment
  - Some patients may advance to higher intensity levels
  - Minimum intensity level to obtain reasonable efficacy is about 17%

End of Treatment

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- When countdown timer reaches 0:00 min/sec intensity immediately drops to 0.0%
- Max intensity is displayed on LCD and should be noted on Treatment Form and in Doctor's notes
- Post treatment pain scores and other metrics should be noted on treatment form and in Doctor's notes
- Gently peel electrodes off of skin
- Place needle side of electrodes together and dispose of in Sharps Disposal
- 1.5" diameter pink circle with 1014 dimple marks will appear at treatment site
- 50% of patients have several tiny drops of blood present
- Clean with an alcohol prep – no dressing is necessary
- Pink circle resolves typically within 2 hours; for patients with sensitive skin, pink circle may take up to 48 hours to resolve