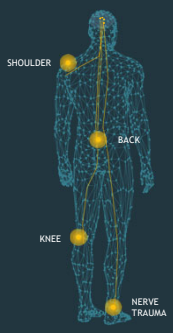
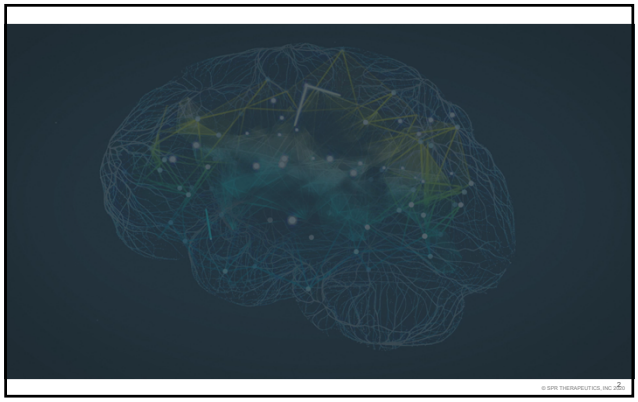
Breakthrough Treatment for Pain™

SPRINT®
PNS SYSTEM

David H. Rustom, MD
Clinical Assistant Professor WSU-SOM
Clinical Assistant Professor MSU-COM
Faculty Physical Medicine and Rehabilitation Residency Program
Faculty Sports Medicine Fellowship
Attending Interventional Pain and PMSR
Rehabilitation Institute of Michigan/Detroit Medical Center
Detroit, Michigan
drustom@dmc.org





How SPRINT's 60-Day PNS Treatment May Recondition the CNS

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Pathway to Chronic Pain

Inciting Event	• **Neural Signaling Changes** • *Increased abnormal and spontaneous afferent signaling* • *Pain that endures after normal tissue healing*	• **Central Sensitization:** • *Sustained changes in central pain processing* • *Hypersensitivity to normal inputs*	• **Maladaptive Cortical Plasticity** • *Unbalanced sensory inputs lead to cortical remapping* • *Imbalance in nociceptive processing*

(Kuner and Flor, Nat Rev, 2017; Devor, Exp Brain Res, 2009; Latremoliere and Woolf, 2009; Moseley and Flor, 2012)

SPRINT PNS (60 days)	• **Improve Neural Signaling** • *INCREASE HEALTHY afferent signals in non-pain nerve fibers*	• **Modulate Sensitization** • *MODULATE central pain processing* • *REDUCE hypersensitivity to normal inputs*	• **Recondition Cortical Processing** • *REBALANCE sensory inputs to restore healthy cortical processing of nociceptive signals*

Peripherally Induced Reconditioning of the CNS

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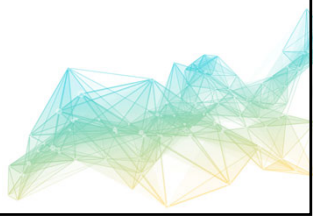
Percutaneous PNS Evolution



PNS Then and Now

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THEN	NOW
• Neurosurgical exposure/procedure	• Percutaneous intervention
• Contact positioning critical	• Ultrasound guidance
• Nerve injury/fibrosis concerns	• Remote lead placement
• Focus on spinal cord stimulation	• Ease of use
• Permanent and invasive	• Low infection risk
• Neuropathic focus	• Durable relief following lead withdrawal
• Last resort therapy	• Applications beyond neuropathic pain
	• Early intervention

Long Held Beliefs are Changing

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- Pain Relief without paresthesia IS possible
- Anatomic vs physiologic lead placement IS beneficial
- Lower amplitudes MAY BE more effective than max tolerated
- Positive response to a nerve block is NOT predictive of PNS outcomes
- Remote lead placement CAN preferentially activate targeted nerve fibers
- Motor activation CAN result in sustained pain relief
- Medial branch stimulation VERSUS ablation may provide relief of low back pain
- Sustained relief IS commonplace following a 60-day PNS treatment

Rethink Your Pain Strategy™

60-day implant period

No permanent implant

FDA-cleared for the treatment of chronic and acute pain

Pain relief is significant and sustained for most patients

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Clinical Evidence

Efficacy of 60-Day PNS Treatment

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Across 30+ peer-reviewed publications regarding percutaneous PNS-related clinical trials, many of which were funded in part by the Department of Defense (DoD) and the National Institutes of Health (NIH):

75% of patients reported **SIGNIFICANT pain relief**.

75% of patients reported **SUSTAINED pain relief**.

Clinical Evidence Highlights

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- **30+ peer-reviewed published articles** since 2001
- **3 Randomized Controlled Trials** (RCTs)
  - Christopher A. Gilmore, MD et al, Percutaneous Peripheral Nerve Stimulation for the Treatment of Chronic Neuropathic Post-Amputation Pain: A Multi-Center Randomized Placebo-Controlled Trial. Regional Anesthesia and Pain Medicine. 2019
  - Wilson, R.D., Gunzler, D.D., Bennett, M.E., & Chae, J. (2014). Peripheral nerve stimulation compared with usual care for pain relief of hemiplegic shoulder pain: a randomized controlled trial. *American journal of physical medicine & rehabilitation/Association of Academic Physiatrists, 93(1), 17*
  - Chae, J., David, T.Y., Walker, M.E., Kirsteins, A., Elovic, E.P., Flanagan, S.R., & Fang, Z.P. (2005) Intramuscular electrical stimulation for hemiplegic shoulder pain: a 12-month follow-up of a multiple-center, randomized clinical trial. *American journal of physical medicine & rehabilitation, 84(11), 832-842.*
- **> $30M in DoD/NIH funding**
- **Conference Awards**

  CNS 2020 – Top Abstract Award – Reduction of Opioid use for Low Back Pain – Dr. Mehul Desai

  ASRA 2019 – Best of Meeting Award – 12-month Relief of Post-Amputation Pain Following Treatment With SPRINT PNS System – Dr. Chris Gilmore

  ASPN 2019 – Best Overall Abstract Award and **Clinical Science Research Award** – 12-month Relief of Post-Amputation Pain Following Treatment With SPRINT PNS System – Dr. Chris Gilmore

  NANS 2020 – Best Poster For PNS Group – Treating Greater Trochanteric Pain Syndrome with Ultrasound Guided Peripheral Nerve Stimulation - Dr. Katie Guran

SPR 10

Sustained Pain Relief

Percutaneous PNS vs Conventional Care for Hemiplegic Shoulder Pain

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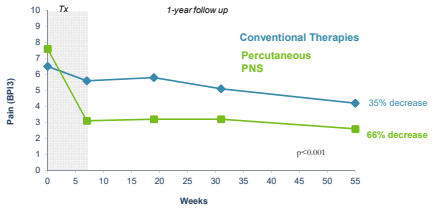
First Percutaneous PNS Randomized Controlled Trial
…First demonstration of Sustained Pain Relief

This RCT utilized a 4 lead approach to activate the muscles surrounding the shoulder joint

78% Reported Relief 12 months after Treatment



Chae, et al (2005)

SPR 11

Chae Results Replicated in Single Lead RCT

Percutaneous PNS vs PT in the Management of Hemiplegic Shoulder Pain

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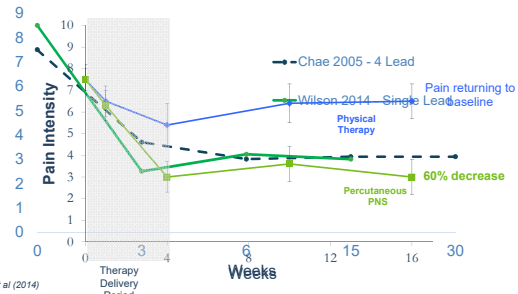

Wilson, et al (2014)

SPR 12

Percutaneous PNS of the Medial Branch

PNS of Medial Branch Nerves to Treat Low Back Pain

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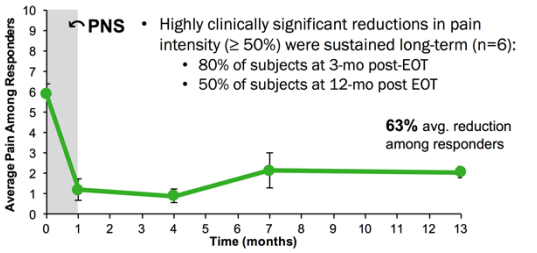

- Highly clinically significant reductions in pain intensity (≥ 50%) were sustained long-term (n=6):
  - 80% of subjects at 3-mo post-EOT
  - 50% of subjects at 12-mo post EOT

63% avg. reduction among responders

Gilmore et al. 2019

Opioid, Pain, and Disability Reduction

PNS of Medial Branch Nerves to Treat Low Back Pain

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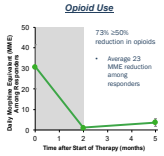
Results at 3 months post EOT:

- 73% (8 of 11) reported ≥50% reduction in opioid consumption
- *Avg. 23.1 MME reduction among responders*
- *Clinically significant reductions in Pain, ODI and Pain Interference*

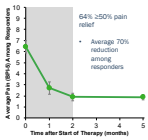
Opioid Use



73% ≥50% reduction in opioids

- Average 23 MME reduction among responders

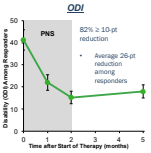
Pain



64% ≥50% pain relief

- Average 70% reduction among responders

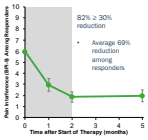
ODI



82% ≥ 10-pt reduction

- Average 26-pt reduction among responders

Pain Interference



82% ≥ 30% reduction

- Average 69% reduction among responders

Conclusion:

- Percutaneous PNS of the medial branch for up to 60 days can significantly reduce opioids, pain and disability without a permanent implant

Gilmore et al. 2019

Percutaneous PNS in Management of Post-Amputation Pain

Results from a double-blind, placebo-controlled RCT

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BMJ Journals

Regional Anesthesia & Pain Medicine

Original article

OPEN ACCESS

Percutaneous peripheral nerve stimulation for the treatment of chronic neuropathic postamputation pain: a multicenter, randomized, placebo-controlled trial

Christopher G
Corey Hunter,[1]
Steven Cohen

RLP
PLP

70% avg. reduction at 12-

Original article

OPEN ACCESS

Percutaneous 60-day peripheral nerve stimulation implant provides sustained relief of chronic pain following amputation: 12-month follow-up of a randomized, double-blind, placebo-controlled trial

Christopher A Gilmore,[1] Brian M Ilfeld,[2] Joshua M Rosenow,[3] Sean Li,[4] Mehul J Desai,[5] Corey W Hunter,[6] Richard L Rauck,[1] Antoun Nader,[7] John Mak,[4] Steven P Cohen,[8] Nathan D Crosby,[9] Joseph W Boggs[9]

Study Sample Size: n=28

Percutaneous PNS Shows Reduced Opioid Use

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In low back pain:

- At 3 months following 60-day percutaneous PNS therapy 73% (n=8/11) reported ≥50% reduction in opioid use (average reduction 82%)
- These substantial reductions were seen even among patients with daily baseline opioid consumption ≥ 50 milligram morphine equivalent (rated by the CDC as high-risk for opioid overdose)

https://www.sprtherapeutics.com/wp-content/uploads/2019/08/MHSRS-2019-LBP-Poster-1.pdf

In post-amputation pain:

- 60-day percutaneous PNS therapy demonstrates 12-month pain relief and 70 percent reduction in opioid use among those taking moderate to high doses

https://rapm.bmj.com/content/early/2019/04/05/rapm-2018-100109

Low back pain: n=11

Post-amputation pain: n=28

SPRINT PNS SYSTEM

SPRINT PNS System and Patient Selection

SPRINT PNS System

SPRINT PNS SYSTEM

Indications for Use

The SPRINT® Peripheral Nerve Stimulation (PNS) System is indicated for up to 60 days in the back and/or extremities for:

- 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

The Sprint PNS System is not intended to treat pain in the craniofacial region.

Chronic Pain Applications

- Complex regional pain syndrome
- Neuropathic Mononeuropathy
- Low back pain
- Inoperable joint pain
- Post-amputation pain
- Nerve or plexus trauma
- Meralgia Paresthetica
- Post-operative joint/joint-replacement pain
- Post-herniorrhaphy pain (posterior approach)
- Post decompression/transposition surgery

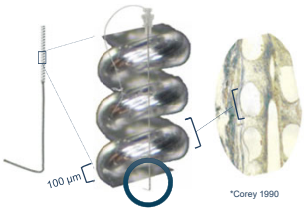
Physicians should use their best judgment when deciding when to use the SPRINT PNS System. For more information see the SPRINT PNS System IFU.

MicroLead Designed to Resist Infection and Migration

SPRINT PNS SYSTEM

The MicroLead™ is a 100µm, 7-stranded wire with a 100µm layer of insulation.

The electrode surface area is 5x longer with more than 2x the surface area of a conventional cylindrical lead



*Corey 1990

Fibrotic ingrowth around the lead is intended to reduce pistoning and the potential for infection.

Excellent Safety Profile

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Adverse Event	SPR Therapeutics' PNS therapy (N=410 leads in 205 subjects)
Skin irritation, erythema, blister, mild tear	13.2% (54/410)
Miscellaneous AEs	5.3% (22/410)
Granuloma	5.1% (21/410)
Pruritus (itching) at electrode exit or bandage site	4.6% (19/410)
Pain after electrode placement	3.4% (14/410)
Pressure sore/skin abrasion from lead connector block	0.7% (3/410)
Infection	0.0% (0/410)**

*Hydrogel improvements have resulted in significant reduction in skin irritation in commercial applications.
**Among data from published studies. A small number of minor infections have occurred outside of the published data.

SPRINT PNS System

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- Least-invasive PNS option
- Safety enhanced by remote placement
- Short term implant may preclude the need for a permanent implant
- SPRINT *extensa*™ first and only dual lead percutaneous PNS system

SPRINT PNS SYSTEM

Scientific Principles Underlying Potential Mechanisms of Action

Sustained Pain Relief Starts Here

SPRINT PNS SYSTEM

- Non-opioid
- Non-ablative
- Motor sparing
- Central and peripheral effects
- Easily reversed, easily repeated
- Amenable to use early in care pathway
- Validated across multiple uses and nerves
- Remote placement reduces nerve trauma risk
- 60-day implant period with very low infection risk
- Durable pain relief obviates need for permanent implant

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If your question is not answered here, please ask your nurse or doctor for more information.

ACTIVITY

- Limit strenuous physical activity & motion (such as twisting, bending, climbing, lifting) near the implant for at least one week. Avoid excessive stress (tugging, pressure, heat) that may damage the stimulation system.
- You may resume exercise and/or physical therapy when directed by your doctor.
- Do not use the system while driving, operating machinery, or during any activity in which sudden muscle tension may put you at risk of injury.
- Never soak the exit site in water. It is okay to shower. Always remove the Pulse Generator (stimulator) and Mounting Pad from your body and keep the Waterproof Bandage over your exit site when showering.
- Review the *Warnings, Precautions & Risks* section in the *Patient Instructions for Use* for potential hazards that may cause injury, discomfort, or damage to your system. Examples include MRI & diathermy.

SYSTEM USE AT HOME

- Make sure that the Pulse Generator is snapped onto a Mounting Pad. The entire surface of the Mounting Pad must be in contact with your skin. Check that all cables are firmly connected.
- Turn stimulation ON for the following amount each day (check one): ☐ 6-12 hours ☐ 24 hours
- If stimulation feels uncomfortable or painful, decrease the intensity to a level that is comfortable.
- Replace & recharge the Pulse Generator battery when the battery icon on your remote shows 1 bar
- Always have one battery charging in the Recharging Base so that you never miss your daily therapy.

CLEANING & CARE

- A MicroLead (thin, thread-like wire) exits your skin under the Waterproof Bandage. Do not pull on it.
- Change the Waterproof Bandage & Cradle when they become soiled, damp, or no longer adhere well to the skin (about every 4-5 days). Take care when removing these to prevent pulling the MicroLead out.
- Clean skin under the bandage with mild soap & water OR wipe skin with an alcohol pad. Allow skin to dry.
- When placing a new bandage, make sure that no part of the adhesive touches the MicroLead or Connector.
- Review the *Changing the Bandage and Cradle* section of the *QUICK START GUIDE* for detailed instructions.
- Check the skin under the bandage for redness, swelling, drainage, or bleeding during bandage changes.
- If any of these signs are present, or if your MicroLead(s) pull out, notify your doctor and an SPR Therapeutics representative: (XXX) XXX-XXXX.

TROUBLESHOOTING

- Review the *QUICK START GUIDE* and the *Appendix B: Troubleshooting* section in the *Patient Instructions for Use* for assistance with your device.
- Additional instructional videos and patient resources are available at the SPR Therapeutics website: https://www.sprtherapeutics.com/quickstart
- If you are running low on any supplies, or if you need help with other questions, problems, or errors on your remote, please call an SPR Therapeutics representative: (XXX) XXX-XXXX.

FACILITY NAME: 1 SPR Therapeutics, Inc. Local SPR Representative Name

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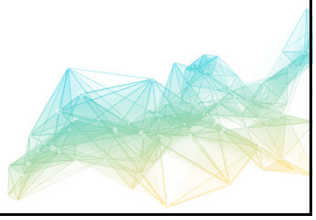
SPRINT Coding, Coverage, and Payment
SPRcare Patient Access Program



Reimbursement for PNS

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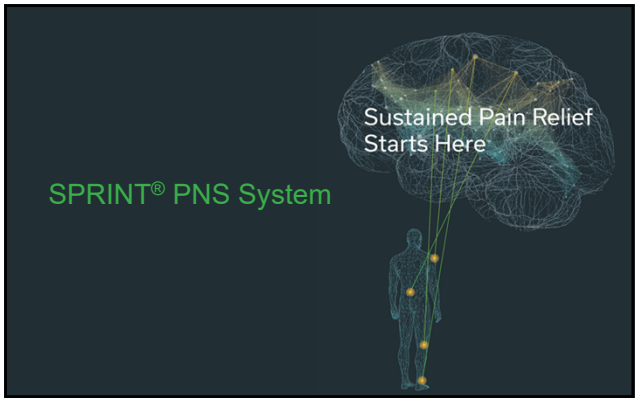
Coding:
- 64555 *Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)*
  - NANS and ASIPP validated code appropriateness for percutaneous PNS lead placement

Coverage:
- Medicare has an active National Coverage Determination (NCD 160.7) allowing the use of PNS when medically necessary in patients with chronic, intractable pain.
- Commercial coverage varies by payer and plan type

SPRINT PNS SYSTEM

SPRcare™

- Facilitating Patient Access and Expanded Payer Coverage
- Leveraging patient-based appeal rights to reduce time to implant
- Push for independent third-party reviews (at payer expense)
- Reduce or eliminate peer-to-peer calls
- SPR will use data generated from the prior authorization and appeals processes to foster positive changes in payer policy



SPRINT™
PNS SYSTEM

*The SPRINT PNS System is cleared for up to 60 days in the back and/or extremities for: (i) Symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain; (ii) Symptomatic relief of post-traumatic pain; and (iii) Symptomatic relief of post-operative pain. The SPRINT PNS System is not intended to treat pain in the craniofacial region.

Physicians should use their best judgment when deciding when to use the SPRINT PNS System. For more information see the SPRINT PNS System IFU.

Most common adverse events are skin irritation and erythema. Results may vary. Rx only.

MKT-000198 [02]