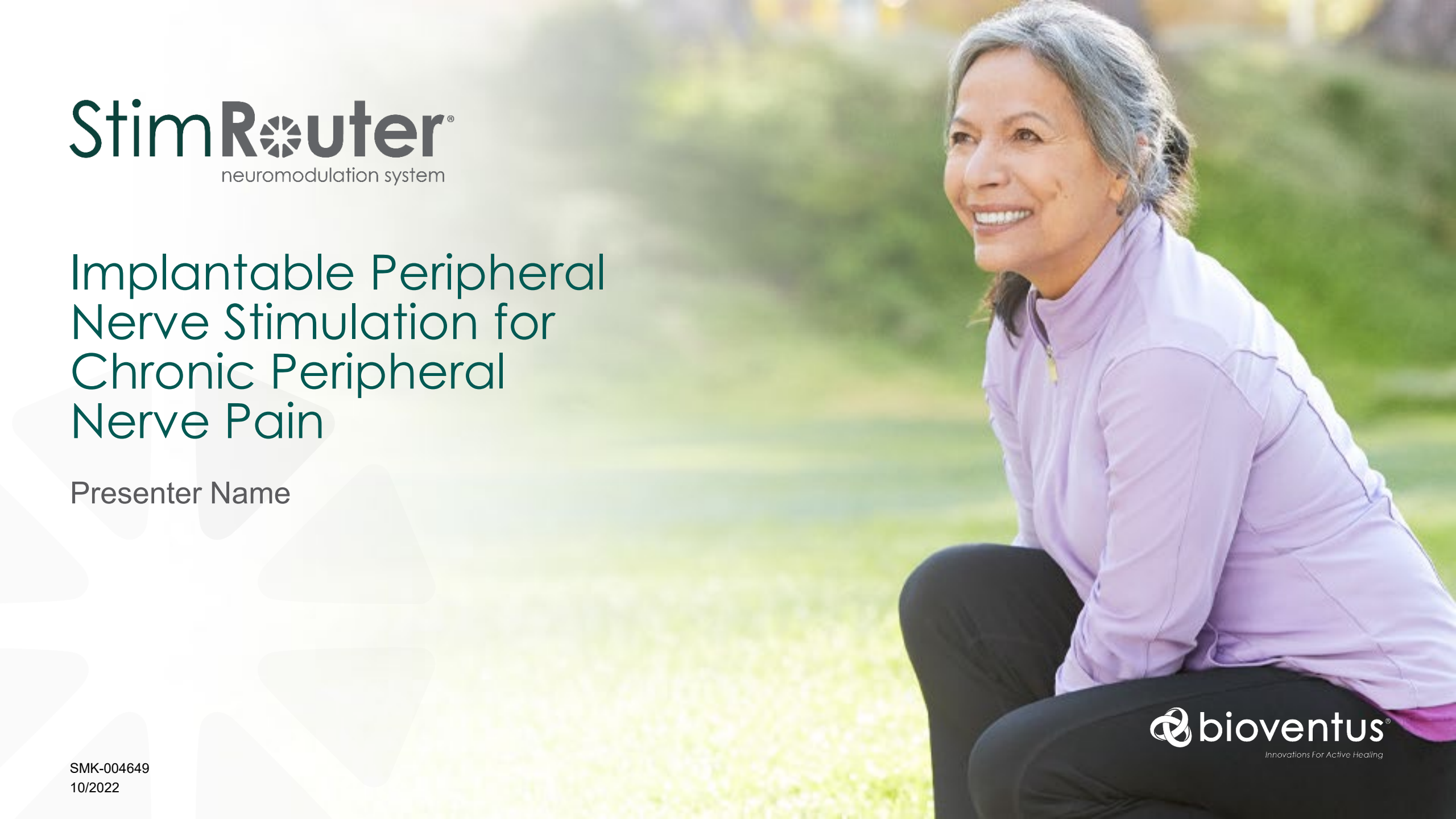
StimRouter®
neuromodulation system

Implantable Peripheral Nerve Stimulation for Chronic Peripheral Nerve Pain

Presenter Name



bioventus®
Innovations For Active Healing

SMK-004649
10/2022

Key Points

- StimRouter® is a small peripheral nerve stimulation (PNS) implant the FDA cleared[1] for treatment of chronic pain of a peripheral nerve origin.* The physician implants the lead on the target nerve responsible for the pain signal while the patient is awake, using local anesthesia.
- Review of relevant, published StimRouter clinical studies & articles.
  - Patient report an average 71% reduction in pain, with a 72% increase in patient activity and significant reduction in opioid use.*

*Oswald J, et al. Prospective case series on the use of peripheral nerve stimulation for focal mononeuropathy treatment. *Pain Manag*. 2019;9(6):551-8.

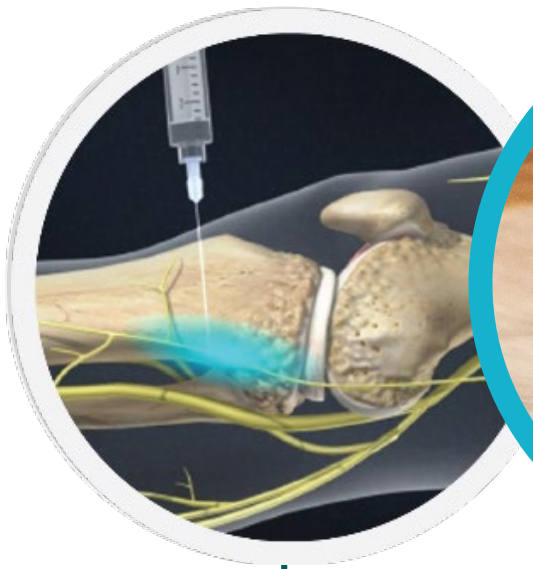
Please visit www.StimRouter.com to download full instructions for use

Clinical Presentations of Chronic Peripheral Nerve Pain

- Complex Regional Pain Syndrome
- Chronic foot pain
- Chronic back pain
- Failed surgery pain – knee, hip, back
- Nerve compression, injury or trauma
- Post-stroke shoulder pain (PSSP)
- Post-amputation pain
- Pelvic pain
- Carpal Tunnel pain

PSSP Application

New Treatment Paradigm: Long-Term Implantable PNS



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Diagnostic Block

Permanent Implantable PNS/StimRouter

Periph. Nerve Surgery

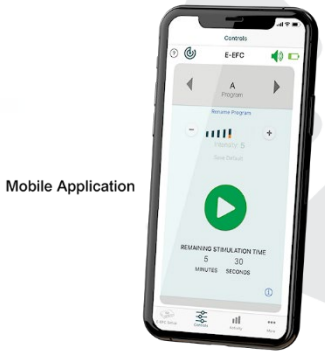
Cryo/Thermal Ablation

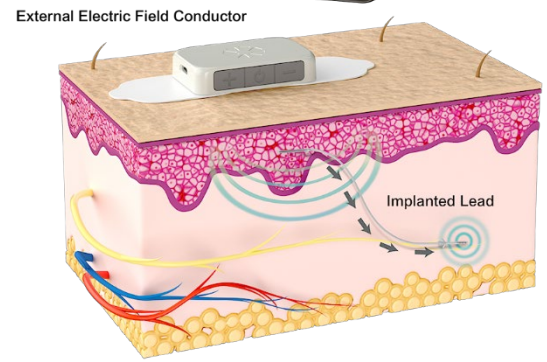
SCS/ITP

Key US centers have moved StimRouter ahead of other chronic pain therapies in the treatment algorithm because of its simple implant technique, non-destructive mechanism of action, and durable results.

StimRouter PNS System

- For patients with chronic intractable pain, refractory to other methods
  of treatment (e.g., analgesics, physical therapy, local injection, surgery) with objective evidence of pathology (e.g., EMG) who are not addicted
  to opioids
- Implanted on the target peripheral nerve responsible for pain signal
  - Implantation is performed through a small incision while the patient is awake, using only local anesthesia
- **Powered externally** through the skin to directly stimulate the peripheral nerve - interrupting the pain signal to alleviate pain.
- **Patient controlled** with small, patient programmer to turn the StimRouter on, off, up, down, and to change stimulation programs.





System Components

External "Electric Field Conduction" (E-EFC) is removed when not in use and recharged nightly

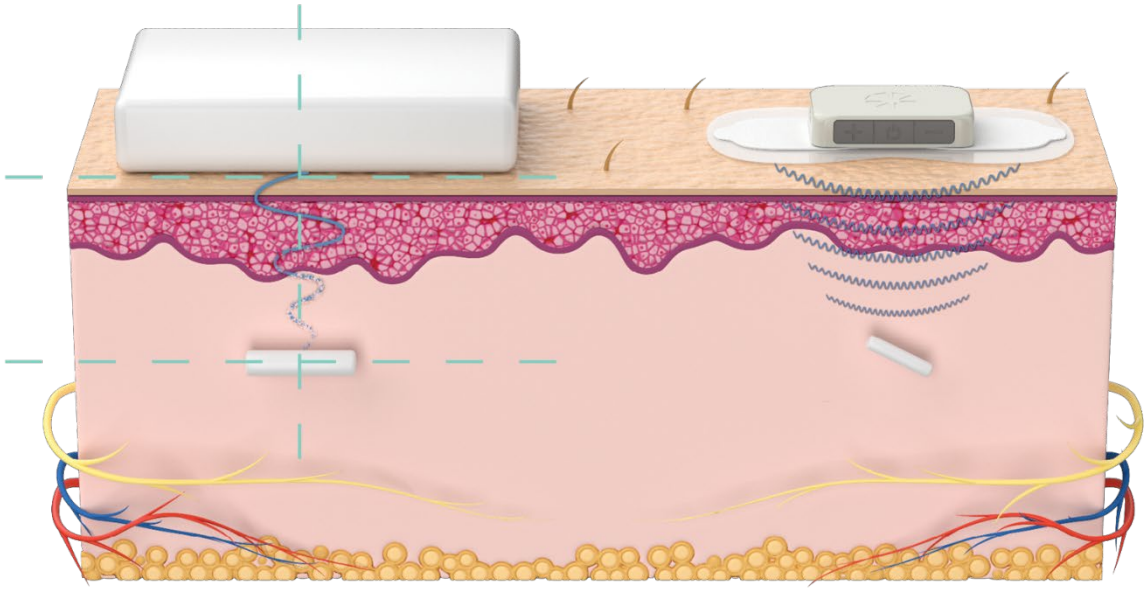
Gel electrode patch replaced every 2-4 days

Mobile App controls stimulation and commands External Electric Field Conductor (E-EFC) to run customized stimulation programs; tracks compliance and usage

Fully Implanted Lead contains three stimulation electrodes, integrated receiver and anchor; 15 cm long

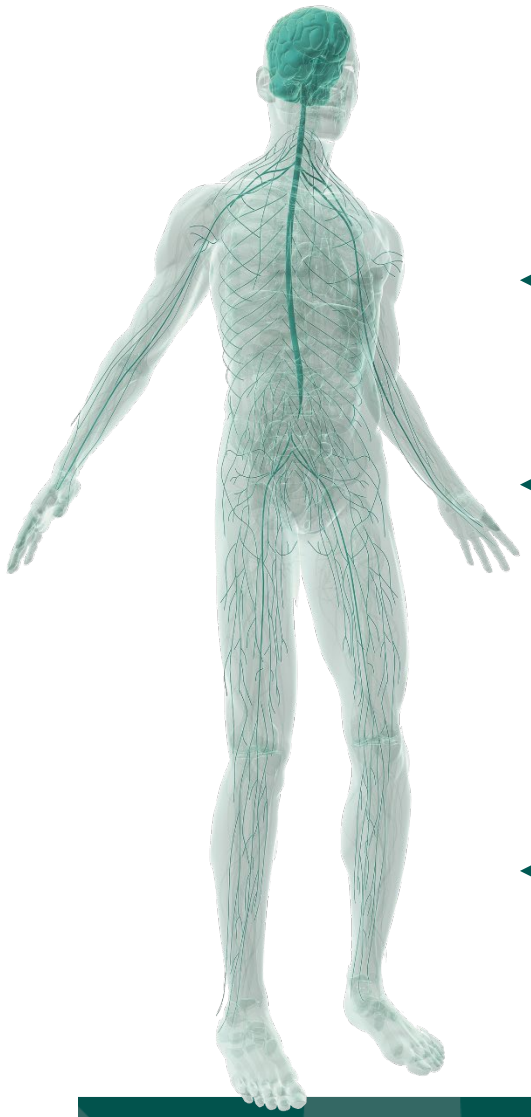
Electric Field Conduction

- Method of energy delivery to power implanted receiver.
- Overcomes attenuation or decay of energy delivery through human tissue with RF.
- Allows for smallest external / wearable of any long-term PNS system.



MAPP Overview Animation

StimRouter Clinical Study[1], Targeted Peripheral Nerves



- 19 peripheral nerves stimulated in pivotal study.
- 30+ peripheral nerves stimulated commercially.

Arm

Ulnar | Median | Radial | Axillary | Suprascapular

Trunk

Ilioinguinal | Intercostal | Pudendal | Iliohypogastric | Coccygeal | Genitofemoral | Superior Cluneal

Leg

Saphenous | Tibial | Femoral | Femoral Cutaneous | Sural

Lead Migration: 0

Infections: 0

Serious Device-Related Adverse Events: 0

[1]Deer T, et al. 2016. *Neuromodulation*. 19:91-100.

Clinical Study Results

Prospective, Multicenter, Randomized, Double-Blinded, Partial Crossover Study to Assess the Safety and Efficacy of the Novel Neuromodulation System in the Treatment of Patients With Chronic Pain of Peripheral Nerve Origin

1 Deer T, et al. Prospective, multicenter, randomized, double-blinded, partial crossover study to assess the safety and efficacy of the novel neuromodulation system in the treatment of patients with chronic pain of peripheral nerve origin. *Neuromodulation.* 2016;19(1):91-100.

Primary Efficacy

At 3-months, the group receiving StimRouter treatment demonstrated a **statistically significant improvement** in pain as compared to the control group ($p<0.0001$)

Primary Safety

No serious adverse events related to the device were reported during the duration of the study (12 months)

Secondary Outcomes

The treatment group had significantly more **favorable outcomes related to quality of life** and satisfaction as compared to those in the control group

50%

of the treatment group rated their **satisfaction 8 or higher** on a 10-point scale

53%

of the treatment group rated their global impression of change in activity limitations, symptoms, emotions and **overall QoL** related to their painful condition between 5-7 on a 7-point scale

31%

of the treatment group rated their **satisfaction at a 10** on a 10-point scale

Post-Market Data – Total Market and Lower Extremity

Future Medicine

JOURNALS BOOKS ABOUT US CONTACT US

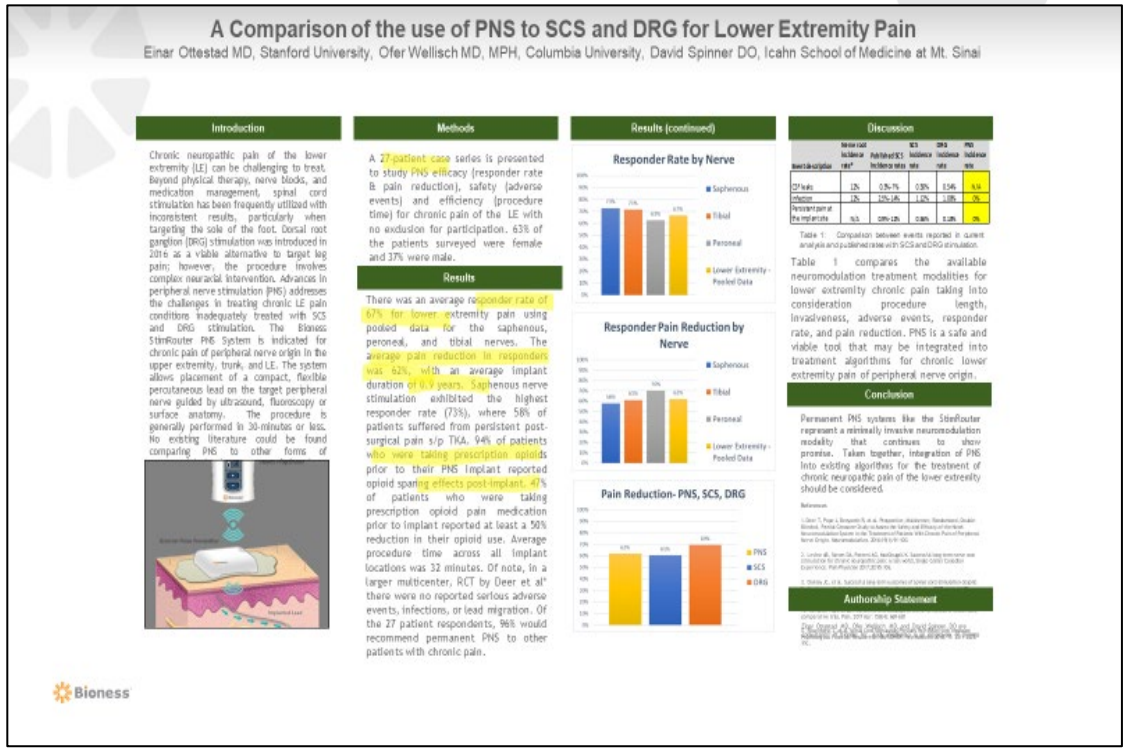
PAIN MANAGEMENT, VOL. 11, NO. 3 | DEVICE EVALUATION

A review of the StimRouter® peripheral neuromodulation system for chronic pain management

Shane M Regnier, Jeffrey Chen, Rodney A Gabriel & Krishnan V Chakravarthy

Published Online: 9 Dec 2020 | https://doi.org/10.2217/pmt-2020-0042

- 18 centers, 15 nerves
- 71% pain reduction
- 72% increase in activity
- 89% had at least 50% opioid medication reduction.



A Comparison of the use of PNS to SCS and DRG for Lower Extremity Pain

Einar Ottestad MD, Stanford University, Ofer Wellisch MD, MPH, Columbia University, David Spinner DO, Icahn School of Medicine at Mt. Sinai

Introduction

Methods

Results

Results (continued)

Responder Rate by Nerve

Responder Pain Reduction by Nerve

Pain Reduction- PNS, SCS, DRG

Discussion

Conclusion

Authorship Statement

Bioness

- PNS compares well with SCS & DRG for relief of lower extremity pain.
- SCS/DRG “rescue”.

StimRouter® peripheral neuromodulation system for chronic pain management. *Pain Manag*. 2021;11(3):227-36.

Ottestad E, et al. A comparison of the use of PNS to SCS and DRG for lower extremity pain. Poster presented at: the North American Neuromodulation Society (NANS) Annual Meeting; January 17-20, 2019; Las Vegas, NV.

Clinical Momentum, Publications

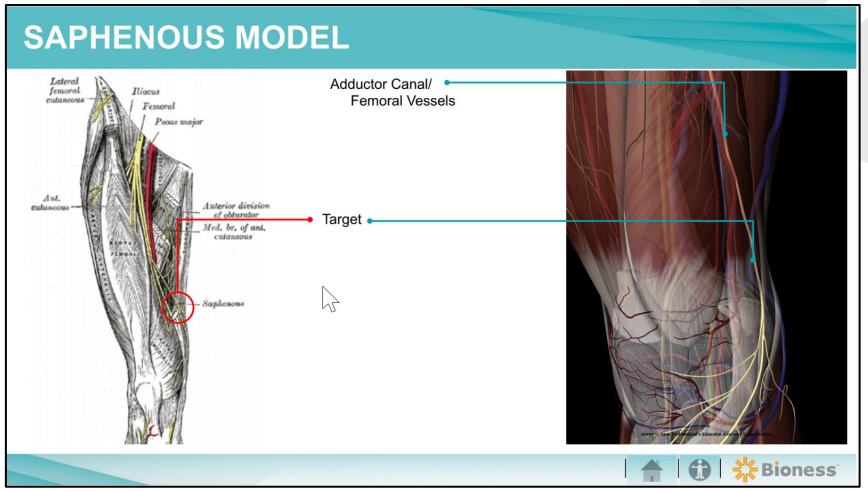
- **Hurdle:** Lumbar radiculopathy stimulating Peroneal Nerve.
- **Mansfield:** “Ortho Shoulder” for patients not candidates for joint replacement.
  - Report expanding to 20 patient study, Q1.[2]
- **Oswald:** 18 centers, 39 implants, 71% pain reduction.[3]
- **Fritz:** Case report on StimRouter for upper extremity CRPS.[4]
- **PNS Supplement:**
  PNS supplement *Pain Medicine*.[5]

1. Hurdle MB, et al. Superficial peroneal responses in patients referred for electrophysiologic evaluation of L5 radiculopathy. *Arch Phys Med Rehab*. 2005;86(9):E17. Poster 63.
2. Mansfield JT, Desai MJ. Axillary peripheral nerve stimulation for chronic shoulder pain: a retrospective case series. *Neuromodulation*. 2020;23(6):812-8.
3. Oswald J, et al. Prospective case series on the use of peripheral nerve stimulation for focal mononeuropathy treatment. *Pain Manag*. 2019;9(6):551-8.
4. Fritz AV, et al. Ultrasound-guided percutaneous peripheral nerve stimulation for the treatment of complex regional pain syndrome type 1 following a crush injury to the fifth digit: a rare case report *Cureus*. 2019;11(12):e6506. doi:10.7759/cureus.6506
5. Peripheral nerve stimulation: update for the 21st century. *Pain Med*. 2020;21(suppl 1):S1-S67.

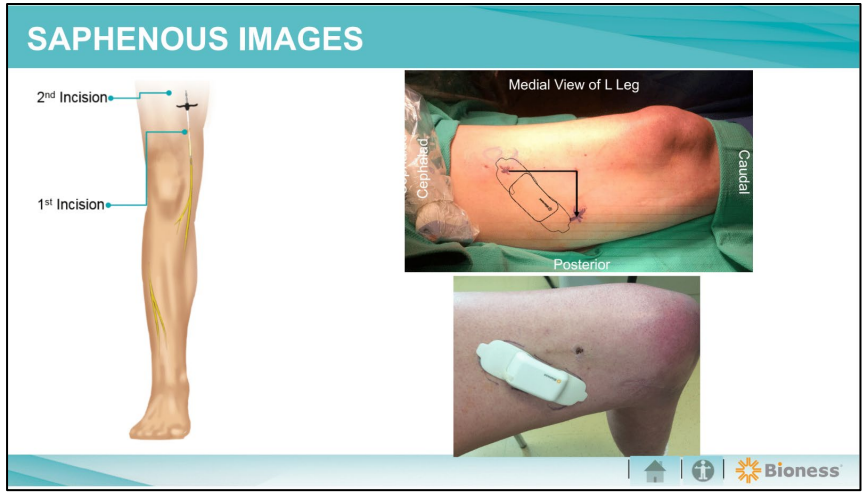
Physician Education: Recurring Customer Q & A

Customers:

1. "What's my approach?"
   - Approaches to Common Peripheral Nerves Guide
2. "Where do I get training?"
   - WAPMU general courses
   - StimRouter private courses
   - Field team private certification (gel models)
   - Peer-To Peer: Connect new & existing implanters

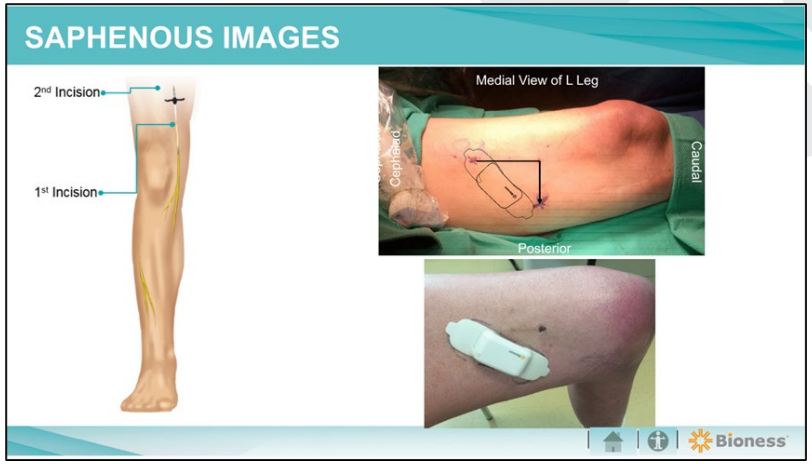


Shoulder Model

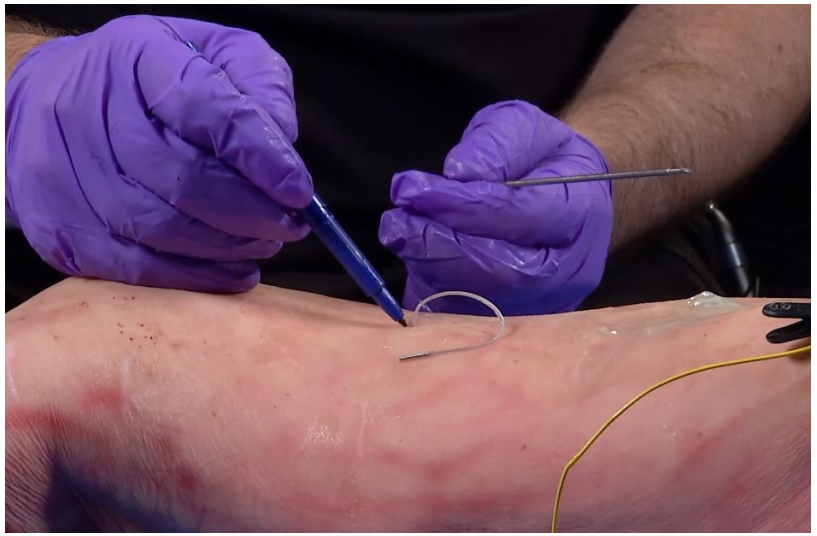


Physician Education

- World Academy of Pain Medicine United (WAPMU):
  - “Approaches to Common Peripheral Nerves:” surgical planning, anatomy, etc.
  - Implant Videos by Peripheral Nerve: 17 instructional videos
  - Private StimRouter sponsored courses
  - WAPMU cadaver training attached to key meetings: NANS
  - On-site training program w/ WAPMU certification
  - WAPMU Bioventus StimRouter Portal URL: www.wapmu.org/bioness-stimrouter-portal Password: “PainDocs2017”
  - Ottestad: Saphenous Nerve Presentation & Saphenous Nerve Implant



Implant Planning



Expert Implant Instruction

Implant & Programming Support

- A Bioventus Field Clinical Manager is present for every implant and programming procedure.
- Field Clinical Managers assist patient with training & trouble-shooting post-implant.
- On-line patient training videos and full-time tech support ready to assist.

Implant Support

Summary

- The StimRouter:
  - Is one of the only long-term implantable neuromodulators that directly stimulates the peripheral nerve
  - Is a safe, reversible, low-cost, minimally invasive, and a long-term solution for patients with chronic peripheral nerve pain
  - Can be used in conjunction with physical therapy and rehabilitation
  - Can be used before irreversible and more costly alternatives (e.g., nerve ablation, SCS)
  - Represents a significant therapeutic tool in light of the opioid crisis

Supported by Peer-Reviewed Published Literature

Adey-Wakeling Z, Arima H, Crotty M, et al; SEARCH Study Collaborative. Incidence and associations of hemiplegic shoulder pain poststroke: prospective population-based study. *Arch Phys Med Rehabil.* 2015;96(2):241-7.e1. doi:10.1016/j.apmr.2014.09.007

Coskun Benlidayi I, Basaran S. Hemiplegic shoulder pain: a common clinical consequence of stroke. *Pract Neurol.* 2014;14(2):88-91. doi:10.1136/practneurol-2013-000606

Deer T, Pope J, Benyamin R, et al. Prospective, multicenter, randomized, double-blinded, partial crossover study to assess the safety and efficacy of the novel neuromodulation system in the treatment of patients with chronic pain of peripheral nerve origin. *Neuromodulation*. 2016;19(1):91-100. doi:10.1111/ner.12381

Evidence-based Review of Stroke Rehabilitation. Hemiplegic Shoulder Pain & Complex Regional Pain Syndrome. www.ebrsr.com/evidence-review/11-hemiplegic-shoulder-pain-complex-regional-pain-syndrome

Forster A. The painful hemiplegic shoulder: physiotherapy treatment. *Rev Clin Gerontol*. 1994;4(4):343-8.

Lindgren I, Jönsson AC, Norrving B, Lindgren A. Shoulder pain after stroke: a prospective population-based study. *Stroke*. 2007;38(2):343-8. doi:10.1161/01.STR.0000254598.16739.4e

Najenson T, Yacubovich E, Pikielni SS. Rotator cuff injury in shoulder joints of hemiplegic patients. *Scand J Rehabil Med*. 1971;3(3):131-7.

Poduri KR. Shoulder pain in stroke patients and its effects on rehabilitation. *J Stroke Cerebrovasc Dis*. 1993;3(4):261-6. doi:10.1016/S1052-3057(10)80071-0

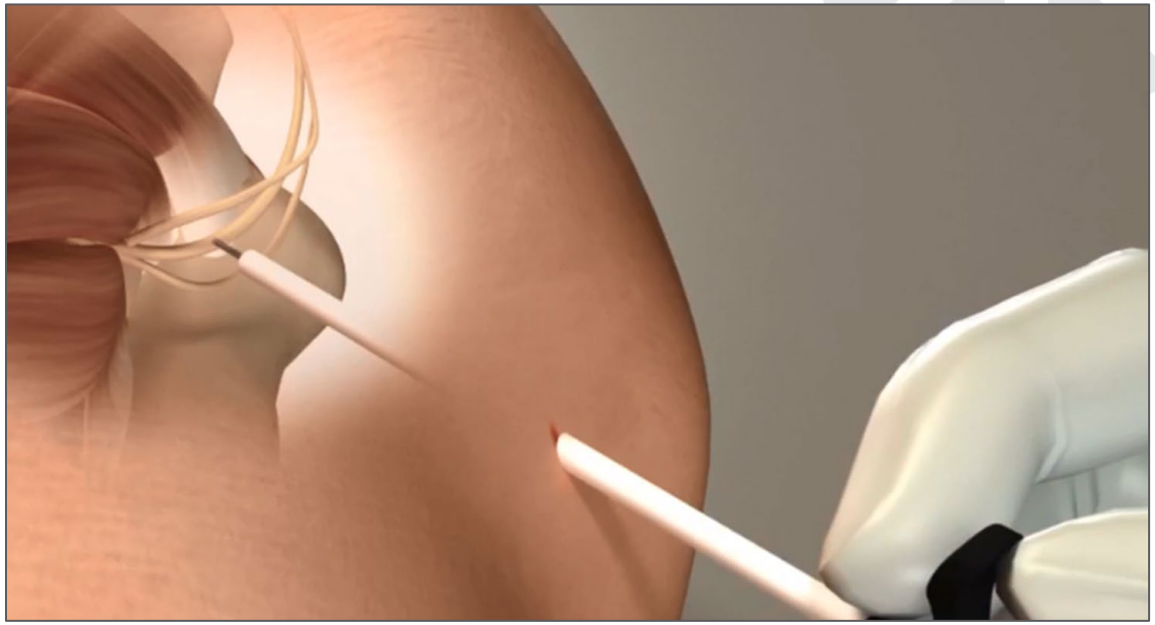
Teasell RW, McRae M. The painful hemiplegic shoulder. *Phys Med Rehab.* 1998;12:489-500.

Thomson S. Spinal cord stimulation's role in managing chronic disease symptoms. Last updated August 3, 2022. www.neuromodulation.com/spinal-cord-stimulation#:~:text=Stimulation%20with%20SCS%20not%20only,to%20communicate%20with%20each%20other

Van Ouwenaller C, Laplace PM, Chantraine A. Painful shoulder in hemiplegia. *Arch Phys Med Rehabil*. 1986;67(1):23-6.

CPT Code 64555 Describes the StimRouter Procedure

- 64555: “Percutaneous implantation of neurostimulator electrode array”
  - When implanting a neurostimulator electrode array, the exact procedure depends on which of the peripheral nerves is being stimulated. The planned insertion site is prepped. Anatomical landmarks are located and separately reportable ultrasound guidance is used as needed to facilitate correct placement of the electrodes. An electrically insulated needle is inserted into the skin and advanced parallel to the peripheral nerve. A power source is connected to the needle, stimulation is applied, and motor and sensory responses are evaluated as the position of the needle is changed until the desired response is achieved. The needle is disconnected from the power source. An electrode array is then passed through the lumen of the needle and positioned in the desired location next to the peripheral nerve. The needle is removed leaving the electrode array in place, which is then attached to an external generator/receiver.

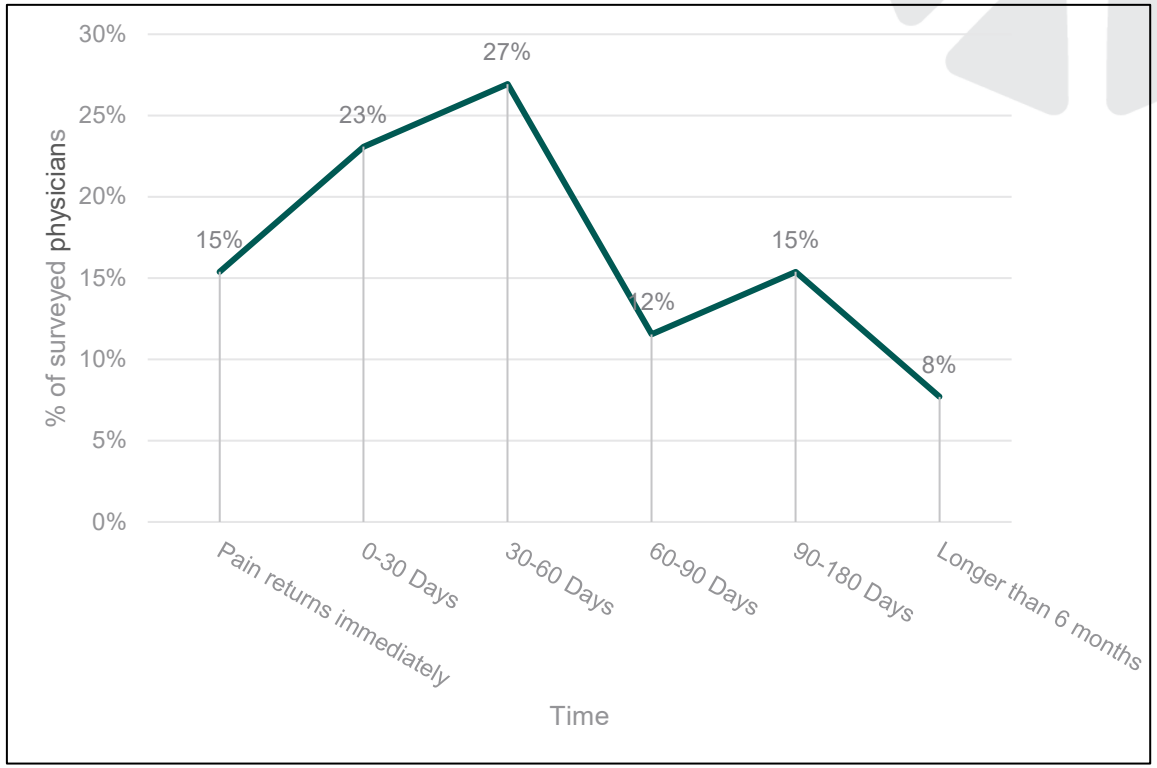


Percutaneous StimRouter Implant:

- Lead electrodes placed on target peripheral nerve
- Lead receiver tunneled to convenient subcutaneous location for easy placement of Electric Field Conductor outside the body to power the implant

Competition – Temporary PNS

- The Myth of Carry-Over Pain Relief Duration
  - 65% of patients had less than 60 days carry-over pain relief after temporary PNS removal
  - 15% responded that their patient's pain returned immediately after removal of temporary PNS
- Lead Fracture Rate
  - Reported to be 7% by SPR
  - 2021 Stanford poster reported 27%[1]
  - Leads must be explanted at 60 days, leaving artifacts in almost 1/3 of patients



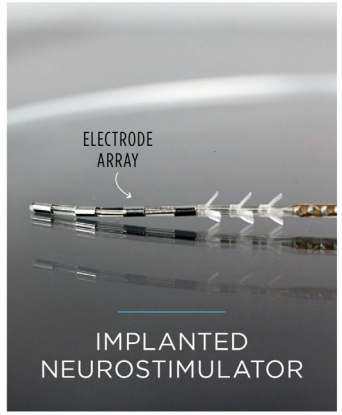
Survey responses to, "For patients who have temporary PNS implants (<60 days), how long does "carry-over" pain relief last before pain returns?" N = 26.

1. Trimble R, Ottestad E, Salmasi V., Hah J, Mackenzie K, Aggarwal A. Lead fracture and retention in a temporary peripheral nerve stimulator system. Poster presented at the North American Neuromodulation Society's 2021 Virtual Meeting, January 15–16, 2021.

Competition – Long-Term PNS

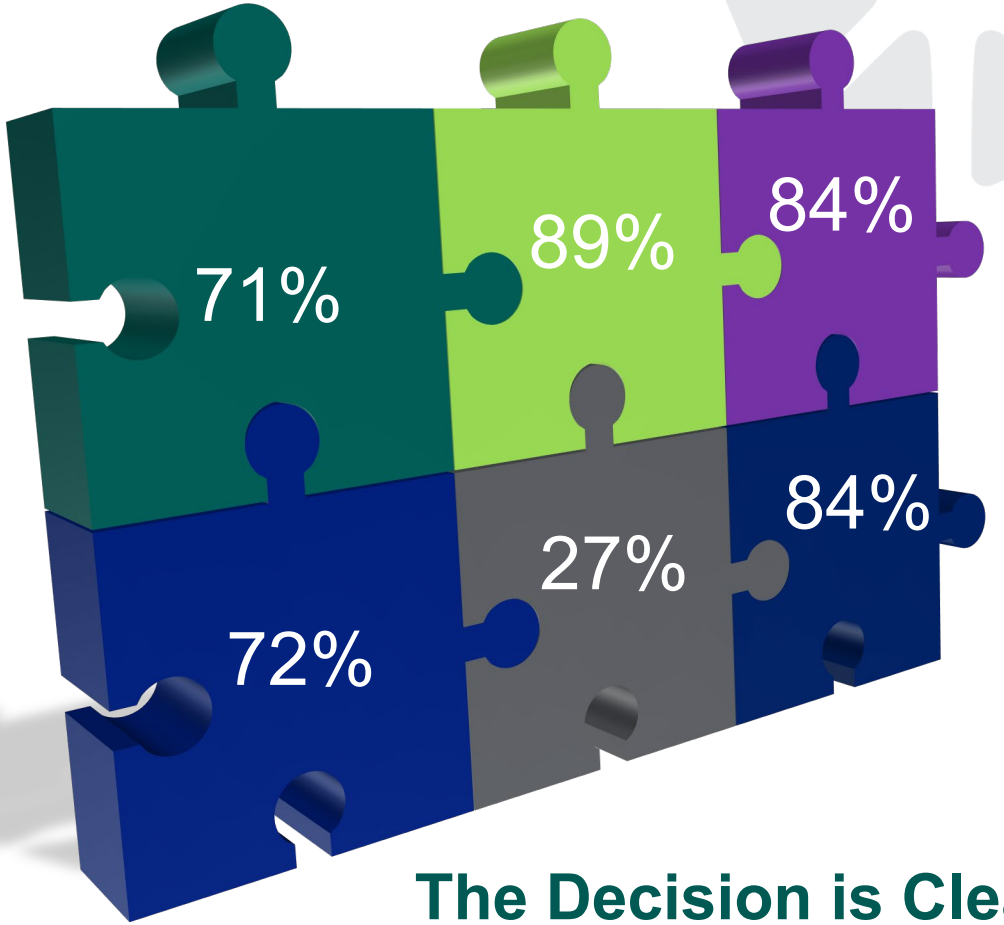
- Nalu™ –
  - RF technology
  - Large, heavy therapy disc
  - Concerns with infection, duration of procedure

- Stimwave –
  - RF technology
  - Lead better suited for SCS



Data Driven Decisions

- 71% average pain reduction[1]
- 89% of patients report at least a 50% reduction in opioid use
- 84% of patients' pain returned within 1 month of temporary PNS[2]
- 72% increase in patient activity level with StimRouter
- 27% lead fracture rate for temporary PNS[3]
- 84% of patients prefer StimRouter to temporary PNS[2]



The Decision is Clear!

1. Regnier SM, Chen J, Gabriel RA, Chakravarthy KV. A review of the StimRouter® peripheral neuromodulation system for chronic pain management. *Pain Manag*. 2021;11(3):227-36.
2. Bioness Inc. Internal Patient Survey (n=84) completed March, 2021; Data on file.
3. Trimble R, Ottestad E, Salmasi V., Hah J, Mackenzie K, Aggarwal A. Lead fracture and retention in a temporary peripheral nerve stimulator system. Poster presented at the North American Neuromodulation Society's 2021 Virtual Meeting, January 15–16, 2021.

Questions

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- StimRouter, Bioness and the Bioness Logo are trademarks of Bioness Inc.
- Individual results vary. Patients are advised to consult with a qualified physician to determine if this product is right for them.
- Important Safety Information and Risks: For Indications for Use, Contraindications, Warnings, Adverse Reactions, Precautions and other safety information please refer to www.stimrouter.com/risks (also available in the StimRouter Clinician's Guide).
- StimRouter User Guide – Patient Resource Center

Implant Animation