



StimRouter[®]

**CONTROL YOUR PAIN,
LIVE YOUR LIFE!**

StimRouter Neuromodulation Therapy
For Chronic Peripheral Nerve Pain

TARGET PAIN AT ITS ORIGIN

The StimRouter® Neuromodulation System is the first implantable neuromodulation device indicated for pain management in adults with severe intractable chronic pain of peripheral nerve origin, excluding the craniofacial region.

WHAT'S THE ADVANTAGE?

- An **outpatient procedure** performed under local anesthesia.
- Targets pain at its **precise origin**, controlled by the patient.
- **No implanted pulse generator.** StimRouter pulse transmitter resides outside the body.
- **Conditional MRI Safety** to minimize restrictions on future diagnostic tests.

ADVANCED DESIGN DELIVERS SIMPLICITY



The Lead:

The implantable lead delivers low-level electrical impulses directly to the site of pain. It is the only component of the StimRouter system that is implanted.

- Three stimulating electrodes and a receiver
- Flexible, thin, 15cm length for deep or shallow implants
- Integrated anchor designed to minimize lead migration

EPT and Electrode Patch:

The External Pulse Transmitter (EPT) delivers Neuromuscular Electrical Field Stimulation (NMEFS) through the electrode patch to the implanted lead.

- Attaches (snaps) onto the disposable gel electrode patch
- Externally worn, low-profile design
- Rechargeable; can last up to two days on one charge



Patient Programmer:

The patient programmer is a small, handheld device that wirelessly controls the EPT.

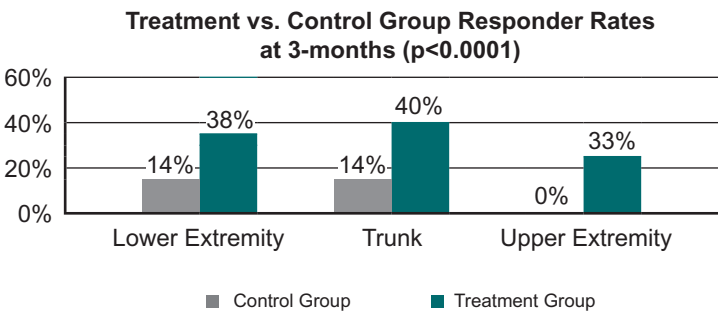
- Stores up to 8 custom stimulation programs
- Tracks compliance and usage
- Allows patients to monitor and manage their stimulation programs and level of stimulation intensity



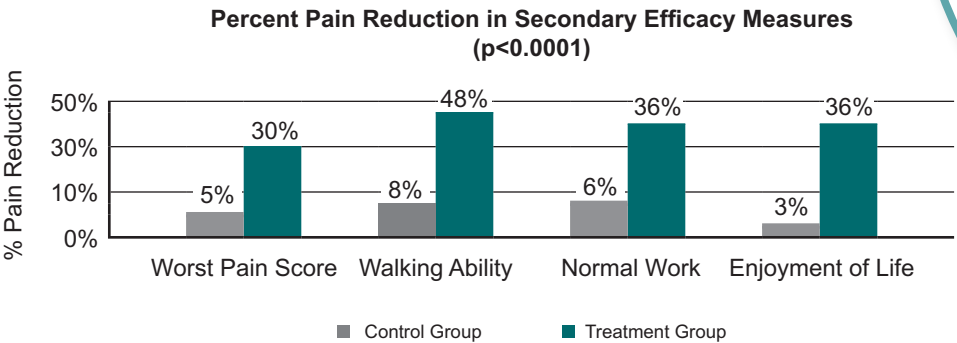
CLINICAL STUDY RESULTS: SAFETY & EFFICACY

Ninety four (n=94) subjects with chronic peripheral pain in the upper extremity, lower extremity or trunk, were implanted with the StimRouter Neuromodulation System for a 12-month study.

- 19 different peripheral nerves were stimulated.



- Primary Efficacy Endpoint defined as a 30% decrease in pain using the StimRouter without an increase in pain medicine.
- At 3-months, the group receiving StimRouter treatment demonstrated a statistically significant improvement in pain as compared to the control group (p<0.0001).



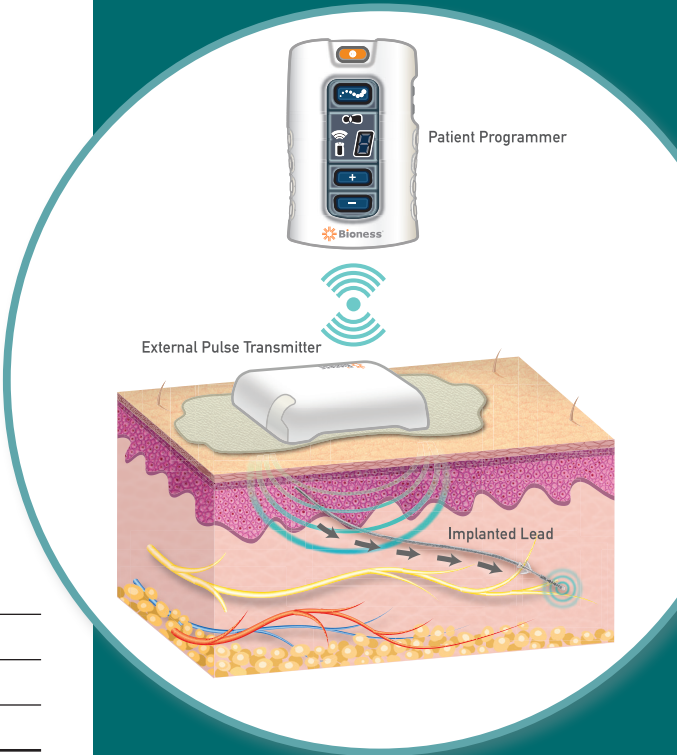
- StimRouter users showed significantly favorable outcomes related to quality of life, pain reduction and satisfaction as compared to those in the control group.
- No serious or unanticipated device related adverse events occurred during active stimulation treatment, which yields a 95% confidence interval of [0, 4.0%) for the SAE rate.
- Over 50% of the treatment group rated their satisfaction at 8 or higher on a 10-point scale, with 0 indicating not satisfied at all and 10 indicating completely satisfied.

StimRouter®

HOW DOES IT WORK?

Applications may include chronic pain conditions located at or relating to:

- Upper or lower limbs
- Entrapment syndromes
- Intercostal neuralgias
- Other peripheral injuries or diseases



QUICK AND EASY PROGRAMMING

StimRouter stimulation amplitude can be set up to 30mA with up to eight (8) custom stimulation programs set via the Clinician's Programmer.

Programming Parameters:

- Frequency: up to 200 Hz
- Pulse width: up to 500 μ s
- Amplitude: up to 30 mA

THE STIMROUTER ADVANTAGE

- Highly versatile implant to target multiple peripheral nerves
- Minimizes surgical and post-surgical complications
- Minimize recovery time and scarring
- Minimizes costs compared to more invasive treatments
- Targets precise area of pain, focal instead of global
- Custom pain management solution controlled by clinician and patient



Bioness Inc.
25103 Rye Canyon Loop
Valencia, CA 91355 USA
Telephone: 800.211.9136 or 661.362.4850
Website: www.bioness.com



Bioness Europe B.V.
Stationsweg 41
3331 LR Zwijndrecht, The Netherlands
Telephone: +31.78.625.6088
Email: international@nl.bioness.com
Website: www.bioness.com

1. Poduri KR. Shoulder pain in stroke patients and its effect on rehabilitation. *J Stroke Cerebrovascular Dis.* 1993. 3:261-6
2. Van Ouwenaller, C, Laplace, P. M., & Chantraine A. (1986) Painful shoulder in hemiplegia. *Archives of Physical Medicine and Rehabilitation*, 67, 23-26.
3. See Bioness_StimRouter_Document11_McRoberts Poster

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®, Bioness and the Bioness Logo® are trademarks of Bioness Inc. in the United States or other countries | www.bioness.com

Rx Only

© 2018 Bioness Inc.



02870