StimRouter®

Peripheral Nerve Stimulation System

For the Treatment of Chronic Pain

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Agenda

- Bioness Introduction
- Technical Overview
- Patient Outcomes
- Clinical Study
- Referral Pathway
- Next Steps

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Mission Statement

“**Bioness** provides neuromodulation technologies that **help improve lives** and restore function for those living with neurological deficit and peripheral pain.”

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Born from the Alfred Mann Foundation

- **Cochlear Implants** - Advanced Bionics
- **Retinal Implants** - Second Sight
- **Insulin Delivery** - Medtronic
- **Cardiac Rhythm Management** - St. Jude
- **Functional Rehabilitation** - Bioness

Technologies designed to allow:

"The blind to see. The deaf hear. The lame walk."

Alfred Mann

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Bioness Portfolio -A Brand You Know

L300 FES System Foot Drop System
2006

L300 Plus FES System for Thigh Weakness
2010

H200 Hand Rehabilitation System
2004

Vector Gait and Safety System
2013

Bioness Integrated Therapy System (BITS)
2014

L300 Go FES System
2017

StimRouter Neuromodulation Therapy for Pain
2015

- 7 FDA-cleared medical devices
- Award Winning Technologies
- 170 Licensed Patents

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Chronic Peripheral Nerve Pain Management

Common Clinical Applications

- Failed surgery pain – knee, hip, back
- CRPS
- Nerve compression, injury or trauma
- Back pain
- Post-stroke shoulder pain
- Spinal cord injury pain
- Foot/neuroma pain
- Post-amputation pain

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Treatment Options | Chronic Peripheral Nerve Pain

Rx Meds/
Opioid Use

Physical
Therapy

Nerve Block/
Ablation

Spinal Cord
Stimulation

Do
Nothing

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Neuromodulation

“The alteration of nerve activity through targeted delivery of a stimulus, such as electrical stimulation or chemical agents, to specific neurological sites in the body.”

ins
International Neuromodulation Society

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Pain Management: Spinal Cord Stimulators

Completely implanted system

Lead placed in dorsal column of spine tunneled to an implantable pulse generator

Rechargeable & primary cell requires surgery to replace battery

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Spinal Cord Stimulators vs PNS

70% Number of Neuromodulation Procedures treated with SCS

6K Off-Label SCS procedures used to treat peripheral nerve pain per year

Diverse etiologies and pathologies;

Many implant locations not easily accessible by SCS

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Post Stroke Shoulder Pain

>10M Number of Stroke Survivors in the United States

800K Number of Strokes Each Year in the United States

Up to **~60%** Number of Stroke Patients Reporting Pain each year

Stroke Recovery Challenges:

PSSP is difficult to treat and limits recovery potential. Early intervention is key.

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Post Stroke Shoulder Pain

Shoulder pain can occur as early as 2 weeks post-stroke but typically occurs within 2-3 months post-stroke.

Contributing Factors

- Subluxation
- Contractures
- Rotator cuff injury
- Spastic muscle imbalance of the glenohumeral joint

Limits motor and functional recovery, ADLs. Decreases QoL.

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Target Pain at its Source

CHRONIC PAIN

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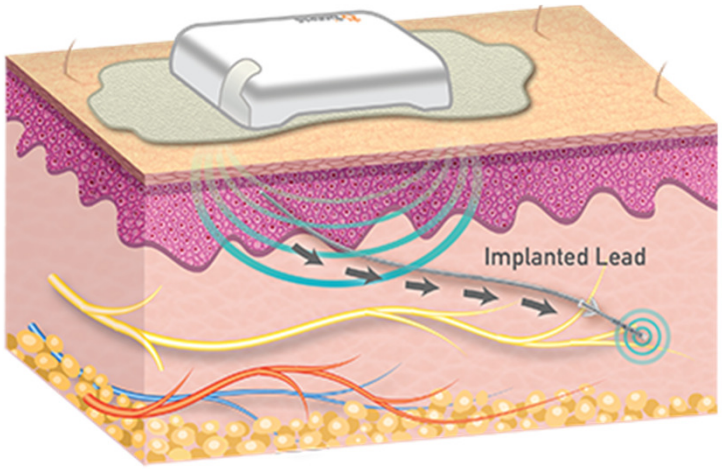
StimRouter Neuromodulation System



FDA cleared, minimally-invasive implant designed to treat **chronic pain of peripheral nerve origin,** below the cranial facial region. The minimally-invasive lead implant procedure is performed **under local anesthesia** through a small incision.

Powered externally through the skin to stimulate the peripheral nerve with a small, focal electrical field - interrupting the pain signal to alleviate pain.

Puts **patients in control** of their pain with a handheld, wireless Patient Programmer.

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System Components

External Pulse Transmitter (EPT) is removed when not in use & recharged nightly;
Gel electrode patch replaced every 2-4 days

Patient Programmer controls stimulation and commands EPT to run up to 8 customized stimulation programs

Lead contains 3 stimulation electrodes, integrated receiver and anchor; 15cm long, fully implanted

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StimRouter Lead

- Only component of the system that is implanted
- Flexible, durable 15cm lead with integrated receiver
- Anchoring mechanism designed to prevent migration
- Three, single channel electrode contacts

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External Pulse Transmitter (EPT)

- Transmits electrical field stimulation to receiving end of lead that is implanted under the skin
- Programmable: Stores up to 8 stimulation programs
- Rechargeable: Can operate ~2 days on single charge
- Attaches to disposable Electrode Patch
- Gel patch adheres to skin to properly position EPT

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Patient Programmer

- Wirelessly controls the EPT
- Turns on/off; Adjusts intensity +/-
- Allows patients to control stimulation, manage programs & intensity
- Tracks compliance & usage
- Visual and auditory indicators
- Rechargeable battery

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Contradictions/Precautions

Precautions

Patients who have a cancerous lesion near the target stimulation point or near the electrode patch. Patients exposed to diathermy. Patient exposed to therapeutic ultrasound.

Exclusions

Demand Cardiac Pacemaker or Defibrillator. Metallic implant in the immediate area of the implant (e.g. shoulder). Patients with Central Pain Syndromes.

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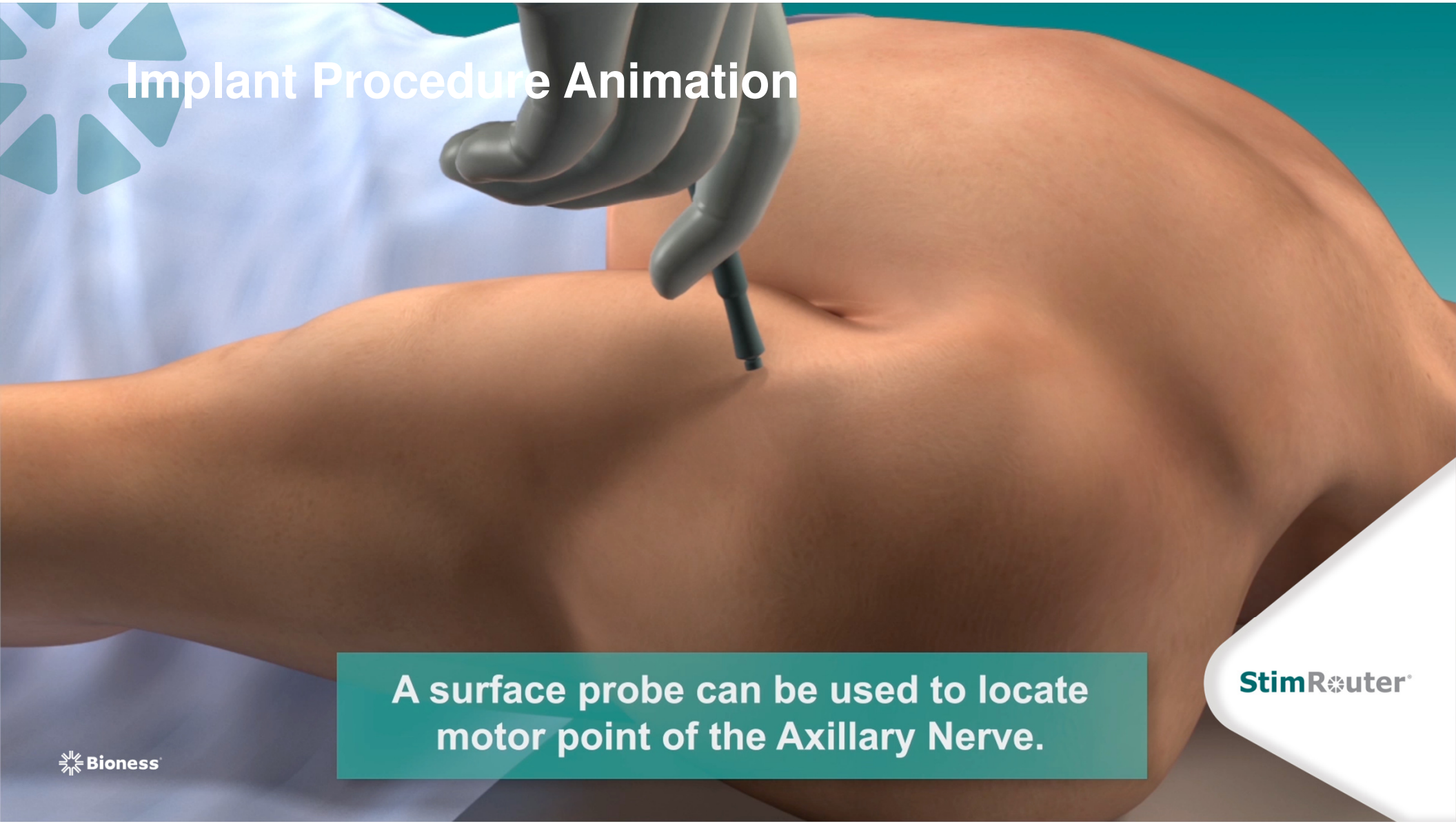
Implant Procedure Animation



Clinical Study Results

Neuromodulation: Technology at the Neural Interface

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

Timothy Deer, MD*; Jason Pope, MD†; Ramsin Benyamin, MD‡; Ricardo Vallejo, MD, PhD§; Andrew Friedman, MD¶; David Caraway, MD, PhD**; Peter Staats, MD††; Eric Grigsby, MD, MBA‡‡; W. Porter McRoberts, MD§§; Tory McJunkin, MD¶¶; Richard Shubin, MD***; Payam Vahedifar, MD†††; Daryoush Tavanaiepour, MD‡‡‡; Robert Levy, MD, PhD§§§; Leonardo Kapural, MD, PhD¶¶¶; Nagy Mekhail, MD, PhD****

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.

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Clinical Study Results

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 quality of life** 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

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Targeted Peripheral Nerves

Arm

Ulnar | Median | Radial | Axillary | Suprascapular

Trunk

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

Leg

Saphenous | Tibial | Femoral | Femoral Cutaneous | Sural

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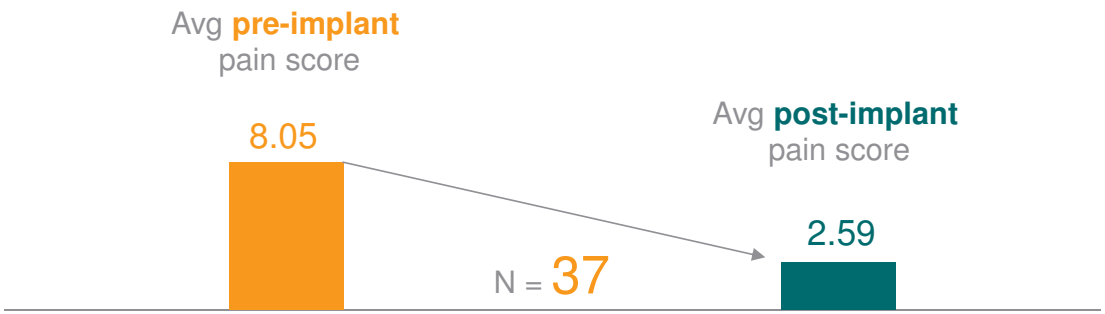
Bioness Patient Survey

15 different nerve locations | Carry-over effect, decreases utilization over time | Data up to 5 years post-clinical study

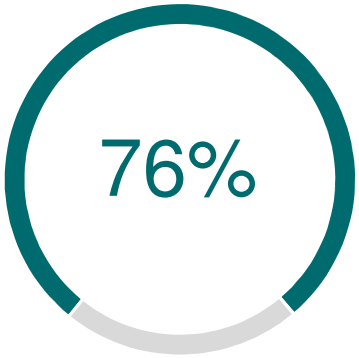


Avg pain reduction

Responder rate

Avg opioid use reduction

N = 15



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Old Pain Algorithm

1	2	3	4	5
Temporary pain relief	Temporary, inconsistent outcomes	Sometimes painful, not durable, more damage to nerve	Invasive surgery, not reversible	Invasive surgery, difficult for many peripheral nerve locations

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Einar Ottestad, MD
Clinical Associate Professor Anesthesiology, Peri-operative and Pain Medicine
Stanford University Hospital, Palo Alto, CA

New Pain Algorithm

1. Diagnostic Block
2. PNS/StimRouter

3. Periph. Nerve Surgery
4. Cryo/Thermal Ablation
5. SCS/ITP

Einar Ottestad, MD
Clinical Associate Professor Anesthesiology, Peri-operative and Pain Medicine
Stanford University Hospital, Palo Alto, CA

Why StimRouter?

Target Peripheral Nerve Pain at its Source

20+ locations implanted, 78% responder rate, 68% pain relief overall, reduced use of Rx medications

Minimally-Invasive

Two small incisions, often a 30 minute procedure, local anesthesia

Durable Pain Relief

Compared to injections and other temporary interventions, StimRouter may provide lasting relief

Reversible and MRI Conditional

MRI scans permitted under certain conditions; Single incision explant procedure if required

Patient Testimonials

LUCINA: “When the doctor turned it on, **the pain went away** and now all I feel is a slight tingling. Now I can **move my arm, lift it, and do exercises** with the help of my therapist and the pain is totally gone.”

West Palm Beach, FL

KAYE: “I was surprised as to how well the StimRouter worked. **It was a life-saver.** When you’re an active person like I am and all of a sudden your body doesn’t work and you’re in constant pain, it’s very tough. Now, I don’t have pain anymore.”

Redondo Beach, CA

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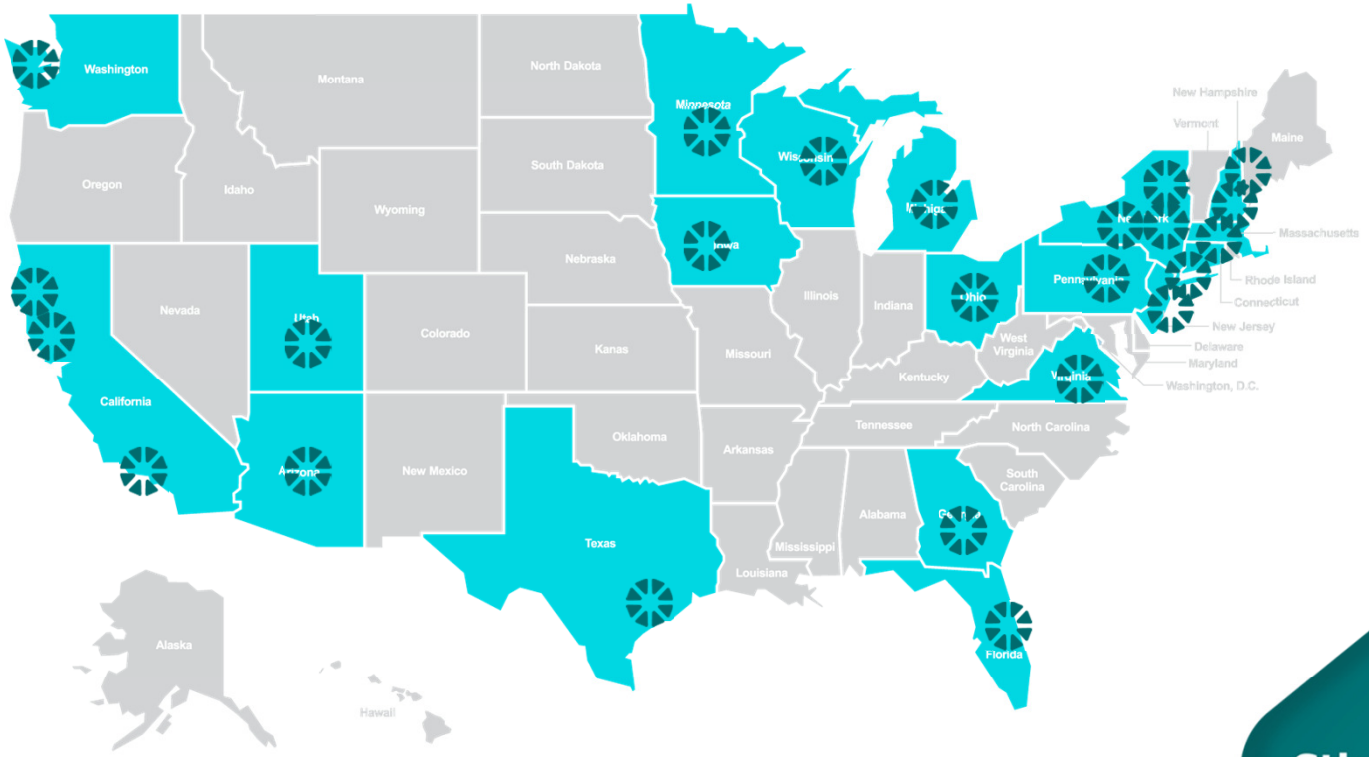
Clinical Centers of Excellence

Stanford University
Mount Sinai
UCLA
University of UT
VCU
Cleveland Clinic
Johns Hopkins



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Deliver StimRouter Outcomes to Your Patients

Bioness Support for Implanting Physicians

Training format customized to your needs

Assistance with technology onboarding/VAC process

Onsite support for first implants and patient programming appointments

Ongoing reimbursement support (documentation, pre-auths, appeals)

Marketing support for patient referrals

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Deliver StimRouter Outcomes to Your Patients

Role of the Referring Physician

1. Refer to Bioness for pre-screening and connection to a local implanter;
   Form 1 authorizes Bioness to contact patient
   -Or refer patients to www.stimrouter.com/dtcinquiries
2. Implanting physician will evaluate for PNS treatment
3. Patient referred back to you post-implant
4. Bioness to track user outcomes

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Kaye Gagnon
StimRouter
Bioness

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Thank you.

Questions?

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