

TARGETED RELIEF. AT THE SOURCE.

PROCLAIM™ DRG NEUROSTIMULATION SYSTEM

PROPRIETARY TECHNOLOGY PATIENT-CENTRIC, PHYSICIAN-FOCUSED

The Proclaim[™] DRG Neurostimulation System is the only FDA-approved DRG technology for the treatment of CRPS I and causalgia of the lower extremities.²⁴

It utilizes a proprietary delivery mechanism and surgical approach uniquely designed to navigate through the intraforaminal ligaments to reach the DRG.²⁴

Modulating the primary sensory neurons within the DRG is important for controlling peripheral pain as the DRG acts as a control center for peripheral sensory nerves. Amplification of incoming peripheral signals can lead to neuropathic pain. Modulating the hyperexcited DRG leads to reduced pain and superior* outcomes for focal chronic pain.

Abbott's proprietary delivery mechanism allows for precise lead placement alongside the DRG, significantly reducing the energy required to provide optimum therapy and enabling low-energy and paresthesia-free treatment.¹

CONTACT AN ABBOTT REPRESENTATIVE TODAY TO LEARN MORE, OR VISIT ABOUTDRG.COM.

EXPAND YOUR REACH TREAT MORE PATIENTS WITH BETTER RESULTS

Dorsal root ganglion (DRG) technology expands the neurostimulation patient pool by enabling you to treat new groups of patients that couldn't be effectively treated before.¹

PROCLAIM[™] DRG NEUROSTIMULATION SYSTEM HAS BEEN PROVEN EFFECTIVE FOR¹:

- Neuropathic pain of the lower extremities after surgical procedures (causalgia)¹
- Causalgia from a traumatic injury of the hip, knee, ankle or foot¹
- CRPS I of the lower extremities¹

RESEARCH SHOWS HIGH PREVALENCE RATES OF CHRONIC PAIN AFTER SURGERY:

8.5%
Hernia
Repair surgery⁴

- 6%

TOTAL HIP ARTHOPLASTY²

10%-40% pelvic floor pain⁵



LOWER EXTREMITY AMPUTATION²

15% – total knee arthroplasty²

5.3% FOOT AND ANKLE SURGERY³

TARGETED RELIEF AT THE SOURCE WITH CONSISTENT, SAFE AND SUPERIOR* OUTCOMES^{1,6-23}

DRG stimulation is clinically proven to provide superior and sustainable pain relief and quality of life improvement for patients with focal chronic pain.¹

It is backed by the ACCURATE clinical trial, the largest randomized, head-to-head, controlled neuromodulation trial for the treatment of CRPS I and causalgia.

IN THE ACCURATE STUDY, DRG STIMULATION WAS PROVEN TO¹:

- Reduce pain an average of 81% at 12 months¹
- Provide persistent pain relief to 86% of patients at 12 months¹
- Provide statistically greater improvements in overall change in physical function, general health and social function at 12 months¹

STUDIED IN DIVERSE CLINICAL SETTINGS AROUND THE WORLD^{1,6-22}



DELIVERED ON A PREMIUM PLATFORM** FOR A BETTER PATIENT EXPERIENCE





PROCLAIM[™] DRG NEUROSTIMULATION SYSTEM BENEFITS INCLUDE:

Proprietary delivery mechanism and surgical approach

Low-energy, paresthesia-free therapy¹

Superior* and sustainable pain relief¹

6.5-year battery longevity at nominal settings^{24***}

Freedom from the hassles of recharging²⁴

Familiar Apple[‡] devices

Upgradeable platform

MR Conditional labeling[†]

*When compared to traditional tonic SCS based on outcomes from the ACCURATE investigational device exemption study.

**Based on new technologies available for DRG therapy.

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- ElDabe S, Burger K, Moser H, Klase D, Schu S, Wahlstedt A, Vanderick B, Francois E, Kramer J, Subbaroyan J. Dorsal root ganglion (DRG) stimulation in the treatment of phantom limb pain (PLP). *Neuromodulation*. 2015;18(7):610-6; discussion 616-7.

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Rx Only

Brief Summary: Prior to using these devices, please review the Clinician's Manual for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use: Spinal column stimulation via epidural and intra-spinal lead access to the dorsal root ganglion as an aid in the management of moderate to severe chronic intractable* pain of the lower limbs in adult patients with Complex Regional Pain Syndrome (CRPS) types 1 and IL**

*Study subjects from the ACCURATE clinical study had failed to achieve adequate pain relief from at least 2 prior pharmacologic treatments from at least 2 different drug classes and continued their pharmacologic therapy during the clinical study.

Please note that in 1994, a consensus group of pain medicine experts gathered by the International Association for the Study of Pain (IASP) reviewed diagnostic criteria and agreed to rename reflex sympathetic dystrophy (RSD) and causalgia, as complex regional pain syndrome (CRPS) types I and II, respectively. CRPS II (causalgia) is defined as a painful condition arising from damage to a nerve. Nerve damage may result from traumatic or surgical nerve injury. Changes secondary to neuropathic pain seen in CRPS I (RSD) may be present, but are not a diagnostic requirement for CRPS II (causalgia). *Dual-lead system with one-year shelf life at 1600-ohms impedance and 24 hours of 20-Hz frequency, 300-µs pulse width, and 0.8-mA amplitude stimulation.

'Within approved parameters.

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Contraindications: Patients who are unable to operate the system, who are poor surgical risks. Patients who have failed to receive effective pain relief during trial stimulation.

Warnings/Precautions: Diathermy therapy, implanted cardiac systems or other active implantable devices, magnetic resonance imaging (MRI), computed tomography (CT), electrosurgery devices, ultrasonic scanning equipment, therapeutic radiation, explosive and flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery, equipment and vehicles, pediatric use, pregnancy, and case damage.

Adverse Effects: Unpleasant sensations, changes in stimulation, stimulation in unwanted places, lead or implant migration, epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space, cerebrospinal fluid leakage, tissue damage or nerve damage, paralysis, weakness, clumsiness, numbness, sensory loss, or pain below the level of the implant, pain where needle was inserted or at the electrode site or at IPG site, seroma at implant site, headache, allergic or rejection response, battery failure and/or leakage. Clinician's Manual must be reviewed for detailed disclosure.

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