Proclaim™ DRG System

Abbott offers the only systems that are FDA-approved to stimulate the dorsal root ganglion (DRG), an effective therapy that provides precise relief* for patients suffering from causalgia or CRPS of the lower limbs.[1,2]

The Proclaim™ DRG neurostimulation system provides clinically superior[2] therapy on a platform designed for patients' convenience.

The intense focal pain associated with causalgia and CRPS of the lower limbs, can often be attributed to nerve damage following an injury or surgical procedure. Examples of these conditions in the groin, hip, knee, ankle or foot leading to chronic pain may include the following:

- A suspected ilioinguinal or genitofemoral nerve injury following a hernia repair or vasectomy
- Abdominal surgery
- Total joint arthroplasties
- Limb amputation
- A surgery or traumatic injury of the hip, knee, ankle or foot

ADVANCED NEUROSTIMULATION TECHNOLOGIES

The Proclaim DRG neurostimulation system comes on a premium platform that includes Invisible Therapy™, a system offering discreet and patient-friendly Bluetooth® wireless technology and Apple‡ mobile digital programming. A range of

other features enhance patient convenience, so they can focus on their lives and not on pain.

LONGER BATTERY LIFE

The Proclaim DRG neurostimulation system offers a battery life of approximately 6.5 years at nominal settings[3] potentially increasing the time between battery replacements and reducing the number of procedures and replacement devices.

UPGRADABILITY

Upgradable technology—only from Abbott—allows patients to benefit from advancements without surgery. As new technologies are approved, patients can receive software upgrades, easily and painlessly.

CONVENIENT PROGRAMMING

The Proclaim DRG neurostimulation system lets patients and clinicians use wireless programming with convenient and familiar technology. Patients can use the Apple‡ iPod‡ controller to:

- Turn stimulation on and off
- Adjust stimulation settings
- Cycle through programs
- Assess IPG battery longevity

Clinicians can use the clinician programmer, featuring an Apple‡ iPad mini‡ mobile digital device and downloadable programming app, to set programming parameters.

MR CONDITIONAL

The Proclaim DRG neurostimulation system is MR Conditional, allowing scans of the head and extremities within approved MRI parameters.

DRG STIMULATION: A CLINICALLY PROVEN THERAPY

DRG stimulation's effectiveness has been proven in the ACCURATE study, the largest[2] randomized clinical trial that compares traditional tonic SCS with DRG stimulation, to manage causalgia and CRPS in the lower limbs. It has been clinically proven to:

- Provide superior pain relief over traditional tonic SCS from causalgia and CRPS[2]
- Provide persistent pain relief to 86% of patients at 12 months[2]
- Reduce pain on average of 81.4% at 12 months[2]

See more clinical evidence.

ST. JUDE MEDICAL™ INVISIBLE TRIAL SYSTEM WITH DRG STIMULATION

The St. Jude Medical™ Invisible Trial System with DRG Stimulation is designed to closely mimic a permanent implant and provides an intuitive way for you and your patients to evaluate whether DRG stimulation is effective for them. Learn more about the St. Jude Medical™ Invisible Trial System with DRG Stimulation.

THE CHOICE FOR BETTER OUTCOMES*

Deliver precise relief to your focal chronic pain patients with the Proclaim DRG neurostimulation system—the choice for achieving superior outcomes* and positive patient experience.

Read more about our approach to chronic pain management.

IPG Specifications

The Proclaim™ DRG IPG has the following physical specifications.

Table 3. IPG specifications

Model	3664
Height	6.09 cm (2.40 in)
Length	4.95 cm (1.95 in)
Thickness	1.34 cm (0.53 in)
Weight	52.0 g (1.8 oz)
Volume	32.0 cm^3 (2.0 in^3)
Power source	Carbon monofluoride/silver vanadium oxide cell
Connector strength	Exceeds EN 45502-1 requirements
Program storage capacity	15 programs with 1 stim set per lead
Upgradeable features	Yes
MRI status*	MR Conditional

* The port plug (Model 7108), which is included in the IPG kit, is an MR Conditional component.

Table 4. Operating parameters for the IPG

Parameter	Range	Steps
Pulse width	40–1000 µs	10 µs (40–500 µs range) 50 µs (500–1000 µs range)
Frequency	4–80 Hz	2 Hz
Amplitude	0–6.000 mA	0.025–0.400 mA

NOTE: The maximum current depends on the impedance, frequency, and pulse width settings.

REFERENCES

*When compared to traditional tonic spinal cord stimulation based on outcomes from the ACCURATE IDE study.
**Based on new technologies available for DRG therapy.
1. Abbott. Data on File. SJM-PDRG-1017-0016
2. Deer, TR, Levy, RM, Kramer, J, et al. (2017). Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. *Pain. 158*(4): 669-681. http://dx.doi.org/10.1097/j.pain.0000000000000814 ACCURATE IDE STUDY, St. Jude Medical. (n=152)
3. St. Jude Medical™ Proclaim™ DRG Neurostimulation System Clinician's Manual. Plano, TX. 2017. Settings: 20 hz, 300 us, 0.8 mA for a dual lead system with 1 yr shelf life at 1600 ohms impedance 24 hrs per day.