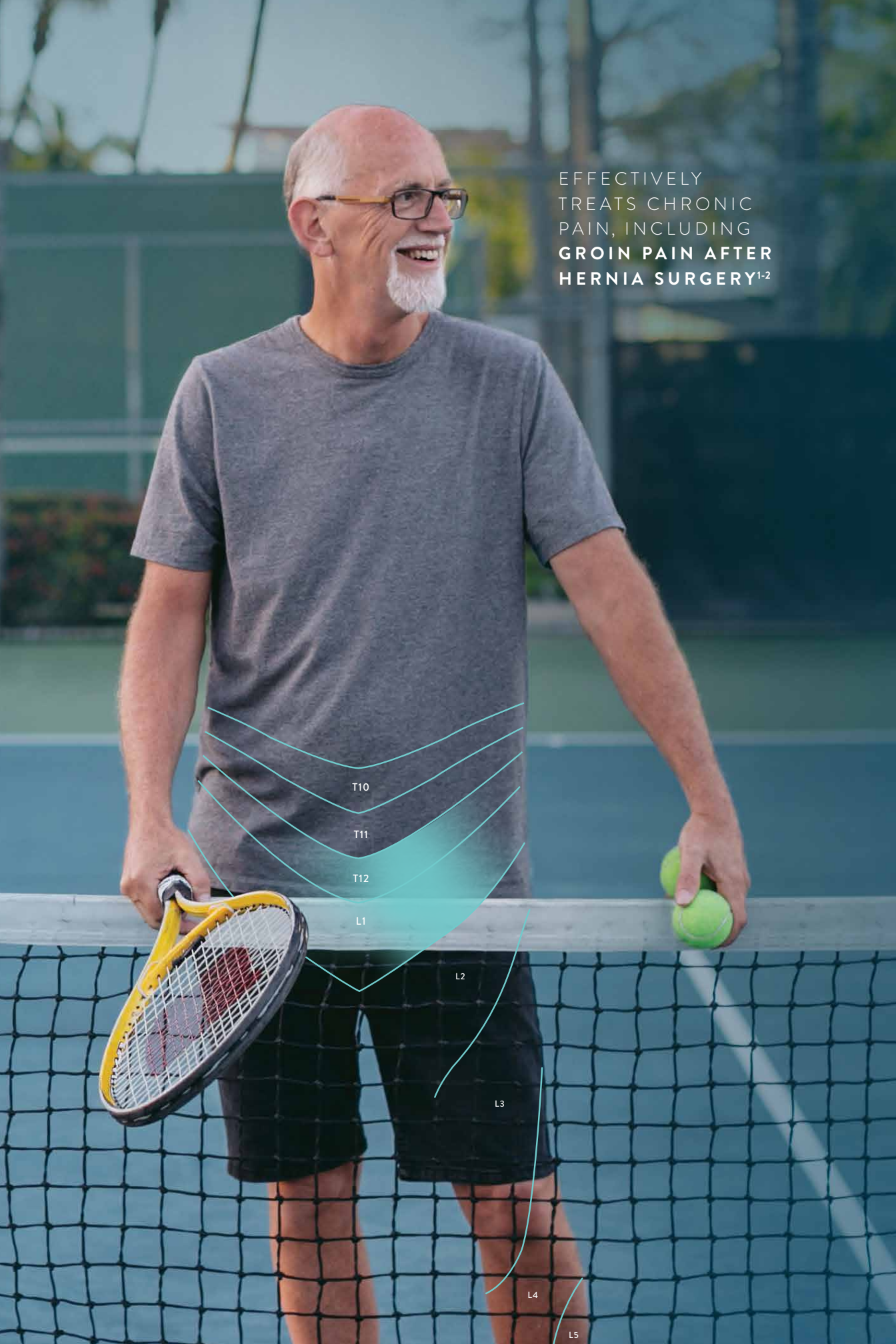
Abbott

PROCLAIM™ DRG THERAPY
FOR CHRONIC PAIN

TARGETED RELIEF. AT THE SOURCE.



EFFECTIVELY TREATS CHRONIC PAIN, INCLUDING **GROIN PAIN AFTER HERNIA SURGERY**[1-2]

TARGETED RELIEF.
AT THE SOURCE.

AT ABBOTT, WE UNDERSTAND THAT CHRONIC PAIN IS PERSONAL, AND IT CAN BE DIFFICULT TO FIND RELIEF.

That's why Abbott continues to develop new treatments for different kinds of pain, including complicated conditions like yours that have not responded to treatment in the past.

If you're experiencing intense pain that started after an injury or a surgical procedure, you might have something called causalgia or complex regional pain syndrome (CRPS).

Common pain areas include:

- Pelvis
- Groin
- Hip
- Knee
- Ankle
- Foot

There's no single test for these conditions, but they're very real and probably due to nerve damage that causes pain signals to fire often and for no reason.

When you have this kind of chronic pain, it can be impossible to focus on anything else. Even more frustrating, these conditions are difficult to treat, so the things your doctor has tried to relieve your pain may not have worked. Standard pain management methods were ineffective; pain medication left you in a fog. There wasn't one clear answer.

UNTIL NOW.

THE RIGHT CHOICE FOR LOCALIZED CHRONIC PAIN

TODAY, THERE'S A NON-OPIOID TECHNOLOGY CALLED DORSAL ROOT GANGLION (DRG) THERAPY THAT'S BEEN PROVEN TO WORK FOR PEOPLE LIKE YOU.[2]

Proclaim™ DRG Therapy is a novel neurostimulation technology that targets and relieves pain at the source. Traditional neurostimulation has been used safely for decades, but it doesn't always work for people with causalgia or CRPS.[2]

Proclaim DRG Therapy has been proven to offer people like you superior* pain relief.[2] The system utilizes recharge-free technology, relieving you from the time and hassles of recharging, unlike rechargeable neurostimulation systems that require frequent charging sessions or numerous office visits to maintain therapy. This means that you can get hassle-free pain relief with a battery that lasts 6.5 years at nominal settings** without ever needing to charge the system.


EFFECTIVELY
TREATS CHRONIC
PAIN, INCLUDING
KNEE PAIN AFTER
SURGERY[1-2]
L2
L3
L4
L5
S1

DRG STIMULATION CAN TREAT CHRONIC PAIN ASSOCIATED WITH CRPS I AND II OF THE LOWER BODY[3]

Pelvis

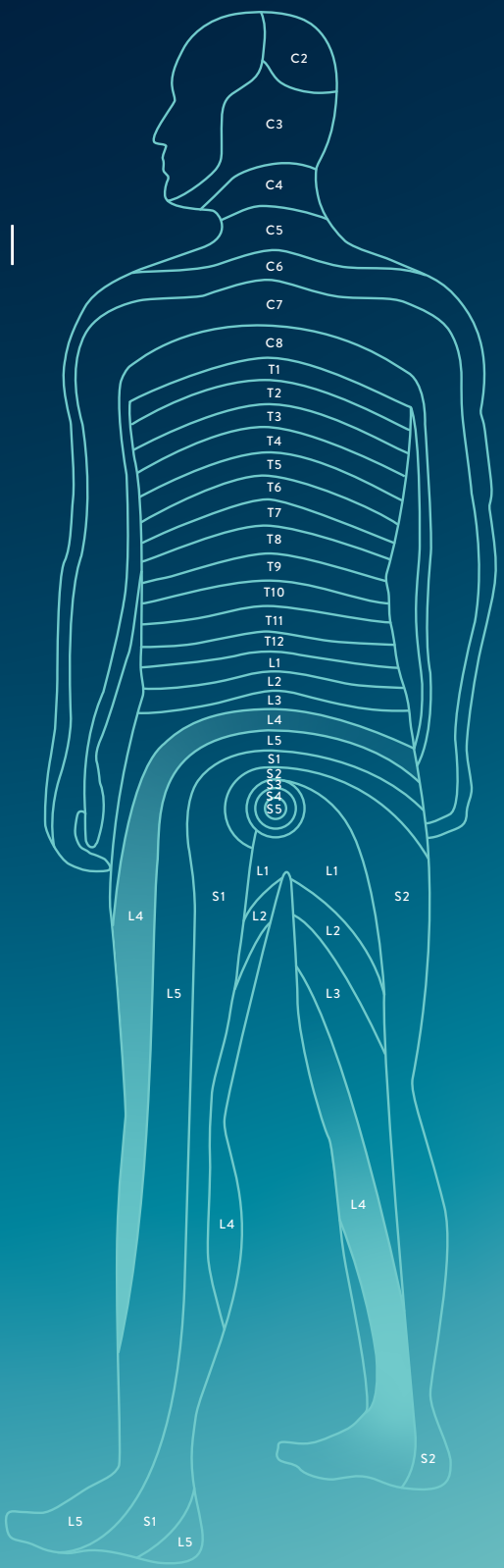
Groin

Hip

Knee

Ankle

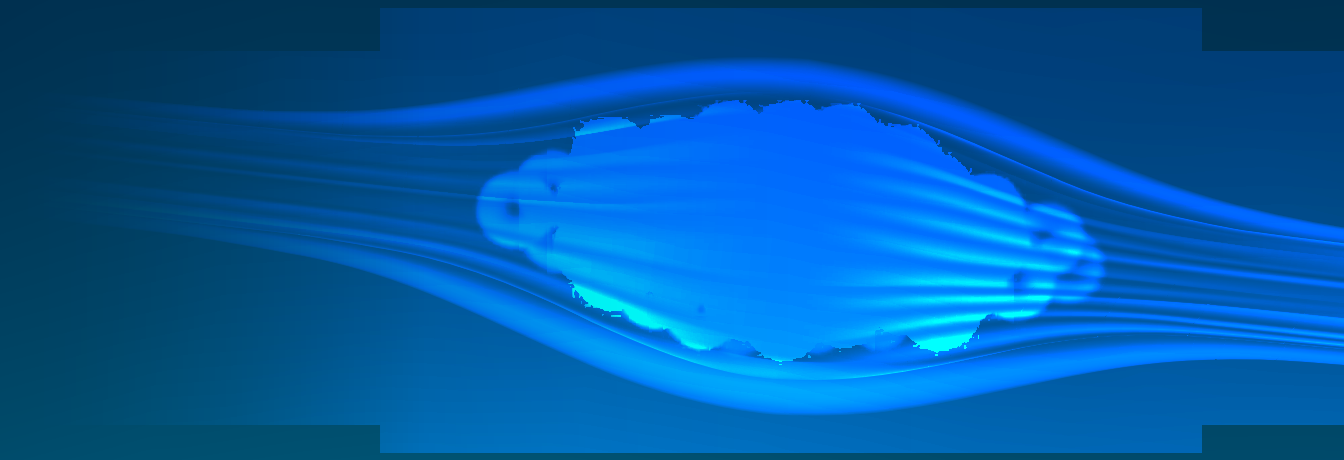
Foot



EVERYONE HAS CLUSTERS OF NERVE CELLS ALONG THEIR SPINE CALLED DORSAL ROOT GANGLION (DRG).

Researchers have found that certain groups of DRG nerves control pain signals from specific areas of the body — such as the pelvis, groin, hip, knee, ankle and foot — where people experience the pain.

HOW IT WORKS



By focusing electrical stimulation specifically on the DRG, we're able to interrupt pain signals before they reach the spinal cord, so you don't feel pain in the same way. Interrupting these pain signals at the source enables the use of low-energy levels on a recharge-free platform and helps eliminate unnecessary stimulation throughout the body, unlike spinal cord stimulation (SCS) systems.[2]

The Result: With Proclaim™ DRG Therapy, you can now have superior* pain relief without the hassles of recharging.

PROCLAIM™ DRG THERAPY HAS BEEN CLINICALLY PROVEN TO[2]:

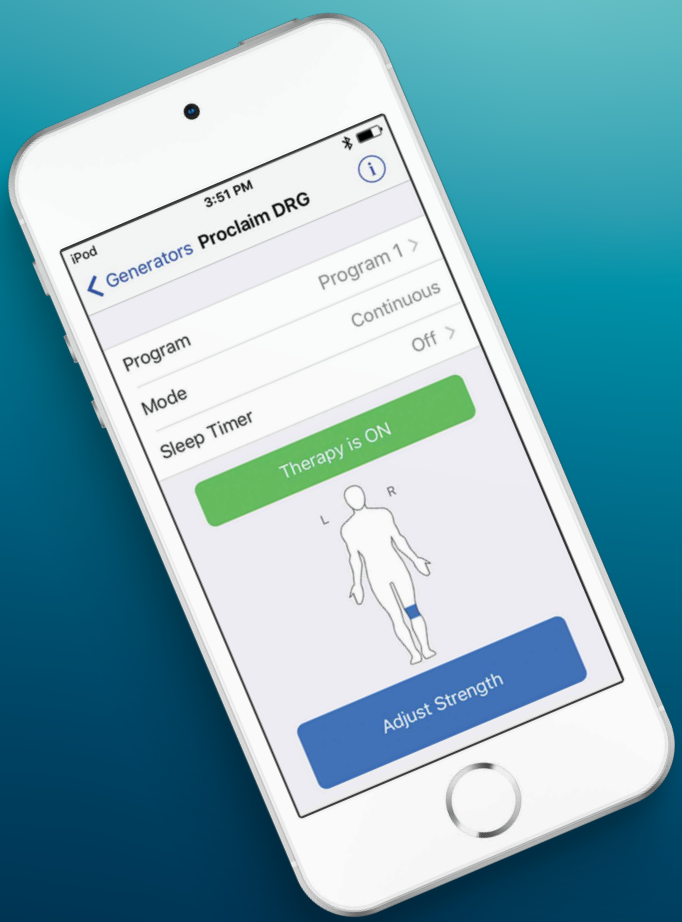
- Provide significant relief from pain as compared to SCS therapy.
- Improve physical function and general health.
- Eliminate the tingling sensation felt with traditional neurostimulation.

MORE THAN 8 OUT OF 10

PEOPLE

EXPERIENCED SIGNIFICANT PAIN RELIEF

AT 12 MONTHS[2]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Proclaim DRG
Program
Program 1
Mode
Continuous
Sleep Timer
Off
Therapy is ON
L
R
Adjust Strength

GETTING STARTED WITH THE **PROCLAIM™ DRG NEUROSTIMULATION SYSTEM**

STEP 1

DOCTOR EVALUATION

Your pain management doctor will determine whether you are a candidate for DRG therapy with the Proclaim™ DRG Neurostimulation System and may introduce you to an Abbott representative who can help answer your questions about the therapy. Your doctor may also recommend a temporary evaluation to determine whether the therapy is right for you.

STEP 2

TEMPORARY EVALUATION

One of the advantages of the Proclaim DRG Neurostimulation System is that you can try it out to see how well it works for you before committing to an implanted system. During the temporary evaluation, you can see whether the therapy:

- Provides meaningful pain relief.
- Improves your ability to perform daily activities.
- Improves your sleeping habits.

STEP 3

IMPLANTED SYSTEM

If at the end of the evaluation period you and your doctor decide that the Proclaim DRG Neurostimulation System is right for you, you can choose to have the system implanted.

EFFECTIVELY
TREATS CHRONIC
PAIN, INCLUDING
CRPS[1-2]

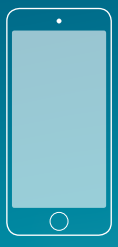
TRY IT FIRST.
THE DRG INVISIBLE TRIAL SYSTEM.

TEMPORARY LEAD

The process begins with a short procedure, often performed at your doctor's office, a hospital or a day surgery center. During this time, your doctor will place thin wires, called leads, which deliver the low-energy electrical pulses that interrupt your pain signals. The leads will be connected to a small external battery.

EXTERNAL BATTERY

During the evaluation, the battery will be worn outside of the body, typically on your lower back. In the recovery room, your Abbott representative will program your system under your doctor's guidance.



PATIENT CONTROLLER

The evaluation will give you an opportunity to see how well the therapy controls your pain throughout the day and during different activities. The typical evaluation period lasts five to seven days, after which you and your doctor will decide whether the Proclaim™ DRG Neurostimulation System is right for you.

PLEASE NOTE: The placement of the leads is a surgical procedure that exposes you to certain risks. Complications such as infection, swelling, bruising and possibly the loss of strength in or use of an affected limb or muscle group (i.e., paralysis) are possible.[3] Be sure to talk to your doctor about the risks associated with the placement of a neurostimulation system.

A SUCCESSFUL EVALUATION. **A LIFE-CHANGING NEXT STEP.**

The next step is to have the Proclaim™ DRG Neurostimulation System implanted in a surgical procedure that is usually completed on an outpatient basis. Much like the temporary system, the three basic components of the implanted system will be familiar to you.

LEADS

Thin wires that deliver electrical pulses from the battery to nerves along the spinal cord.

IMPLANTED BATTERY

A small device, typically implanted in the abdomen or buttock area,[3] that is connected to the leads.

PATIENT CONTROLLER

A handheld device similar to a remote control that enables you to adjust the therapy.

Before the procedure, you and your doctor should review any possible complications as well as the restrictions you will be asked to follow during your recovery and for the long term.

Certain activities can cause the lead or leads to move and cause an unwanted change in stimulation.[3] In general, you should be able to perform your daily activities with less pain over time.


EFFECTIVELY
TREATS CHRONIC
PAIN, INCLUDING
FOOT AND
ANKLE PAIN
AFTER
SURGERY[1-2]
L3
L4
S2
L5
S1

SO EASY TO USE, **YOU MAY FORGET YOU'RE TREATING PAIN**

The Proclaim™ DRG Neurostimulation System with Invisible Therapy™ is:

LOW-ENERGY, SUPERIOR* THERAPY

By targeting relief at the source, the Proclaim DRG Neurostimulation System is able to interrupt pain signals with very low energy.

FAMILIAR TECHNOLOGY

Therapy is managed via a Bluetooth® wireless technology connection and a proprietary app that can be downloaded to your personal Apple‡ mobile digital device*** or an Abbott-provided Apple‡ iPod touch‡ mobile digital device.

RECHARGE-FREE

Unlike rechargeable neurostimulation systems that require frequent charging sessions to maintain therapy, the Proclaim DRG Neurostimulation System gives you hassle-free pain relief with a battery that lasts up to 6.5 years** without ever needing to charge the system.

FUTURE READY

The Proclaim DRG Neurostimulation System features upgradeable technology that can deliver advancements via software updates.

MRI READY

The Proclaim DRG Neurostimulation System allows scanning with a wide variety of medical imaging techniques, including magnetic resonance imaging (MRI).†

EFFECTIVELY TREATS CHRONIC PAIN, INCLUDING **PAIN AFTER AMPUTATION**[1-2]

REMEMBER THIS:
YOU WON'T BE ALONE

The Abbott Care Team offers a wide range of support services for people living with chronic pain. Whether you are just beginning to think about neurostimulation, or you are already finding relief with Abbott therapies, we want you to know we are here for you.

HERE TO HELP

Complete the Action Card attached to the front of this brochure if you would like to be contacted by an Abbott representative to learn more about the Proclaim™ DRG Neurostimulation System. We want you to understand all aspects of the therapy, so we are happy to help.

ONLINE RESOURCES

Visit AboutYourPain.com to find videos and downloadable tools to help you learn more about neurostimulation therapy. You can also sign up to receive emails with helpful tools and information.

FACEBOOK‡ COMMUNITY

When you join our community @AbbottChronicPain, you'll find inspiring stories, helpful tools and timely events for people living with chronic pain and their carers.


EFFECTIVELY TREATS CHRONIC PAIN, INCLUDING **PAIN AFTER TRAUMATIC INJURY**[1-2]
L3
L4
L5
L4
L5
S1

YOU HAVE QUESTIONS. **WE HAVE ANSWERS.**

WILL NEUROSTIMULATION CURE MY PAIN?

Neurostimulation is not a cure for pain, but it is a therapy that can help reduce your pain to a manageable level and help you return to a more normal lifestyle.

WHAT ARE SOME OF THE RESTRICTIONS I MAY HAVE WITH AN IMPLANTED SYSTEM?

Your doctor will give you detailed information about restrictions and activities with your system. As a general rule, however, it is important to restrict the amount of bending, twisting and reaching you do for the first six to eight weeks after surgery.[3] This is the time that the healing is taking place around the leads. There are also some permanent restrictions associated with receiving a neurostimulation system. For example, neurostimulation recipients cannot have diathermy therapy.[3] Be sure to ask your doctor for a complete list of restrictions.

WILL MY INSURANCE COVER THE TEMPORARY AND IMPLANTED DRG SYSTEM?

The temporary system and implanted system are typically covered by most major insurance plans, Medicare and workers' compensation programs. You will need to work with your doctor's office and insurance company to determine your coverage.

WILL I BE ABLE TO REDUCE MY PAIN MEDICATIONS?

Every patient responds differently. Many patients are able to decrease the number of pain pills they take each day, while other patients are able to change the type of medication they take. Please consult with your doctor on specific medication questions.

HOW DO I KNOW THAT DRG STIMULATION WORKS?

The Proclaim™ DRG Neurostimulation System was studied in the largest randomized, head-to-head, controlled neuromodulation trial for the treatment of CRPS and causalgia. After more than a year, the results showed DRG stimulation is the best option for this type of pain.[2]

In diverse clinical settings around the world, Abbott's DRG technology has been studied in over 920+ patients, over 7 years and 18 studies, proving its superiority and sustainability.[1,2,4-19]

*Compared to traditional tonic SCS.

**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.

***Available on eligible Apple‡ mobile digital devices. To find out whether your personal Apple mobile digital device is compatible with Abbott's St. Jude Medical™ Patient Controller app, visit www.NMmobiledevicesync.com/cp.

†Within approved parameters. Refer to the Instructions for Use for full details on the MR Conditional scan parameters.

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Rx Only

Brief Summary: Prior to using these devices, please review the User's Guide for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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 I and II.**

*Study subjects from the ACCURATE clinical study had failed to achieve adequate pain relief from at least two prior pharmacologic treatments from at least two 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).

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 ease 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. User's Guide must be reviewed for detailed disclosure.

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE, DISTRIBUTION AND USE BY OR ON THE ORDER OF A PHYSICIAN.

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