PROCLAIM™ DRG THERAPY

TARGETED RELIEF. AT THE SOURCE.

Patients should be instructed to avoid bending, twisting, stretching, and lifting objects over 2 kg (5 lb) six to eight weeks after implantation of a neurostimulation system.

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AGENDA

01. **Living With Chronic Pain**

02. **Neurostimulation & DRG Therapy**

03. **Proclaim™ DRG Neurostimulation System**

04. **NeuroSphere™ Digital Care**

05. **Steps To Getting Proclaim™ DRG Therapy**

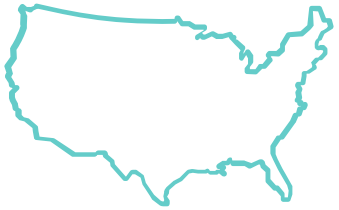
06. **Q&A**

A HEAVY BURDEN

LIVING WITH CHRONIC PAIN

YOU ARE NOT ALONE

Chronic pain is one of the most common reasons Americans **seek medical care** and is associated with restrictions on mobility, anxiety, depression and **reduced quality of life**[1-3]



It is estimated that **50 million** people in the United States **suffer** from chronic pain[4]

$560 billion is the estimated cost of chronic pain, stemming from medical costs, lost productivity and rehabilitation programs[5]

1 IN 10
ADULTS

The WHO estimates that globally, **one in 10 adults** are newly diagnosed with chronic pain each year[6]

Chronic pain affects **more Americans than diabetes, heart disease** and **cancer combined**[7]

People aged **45–64** are the most likely to report pain lasting **longer than 24 hours**[8]

WHAT IS PAIN?

- The body's natural response to harm or possible damage
- Occurs when special nerve endings, called pain receptors, trigger a signal that travels through the spinal cord to the brain
- Signals can be released in response to illness, injury or chemical changes within the body

HOW IS CHRONIC PAIN DIFFERENT?

CHRONIC PAIN

- Lasts longer than six months,[9] or longer than would generally be expected for recovery from a specific disease, injury or surgery
- Sensation varies from person to person and the source of pain may be unknown
- Limited or no pain relief provided by pain medications, surgeries or other therapies

SYMPTOMS CAN INCLUDE:

- Burning feeling
- Stabbing or burning pain
- Tingling or numbness
- Sharp pricks or pinching sensations
- Dull aches or discomfort
- Tenderness

TREATMENTS FOR CHRONIC PAIN

FIRST TIER

- Cognitive and Behavioral Therapy
- NSAIDs
- TENS
- Biofeedback
- OTC Pain Medications
- Rehabilitation Therapy

SECOND TIER

- Opioids
- Nerve Blocks

THIRD TIER

- Radiofrequency Therapy
- Implantable Drug Pumps

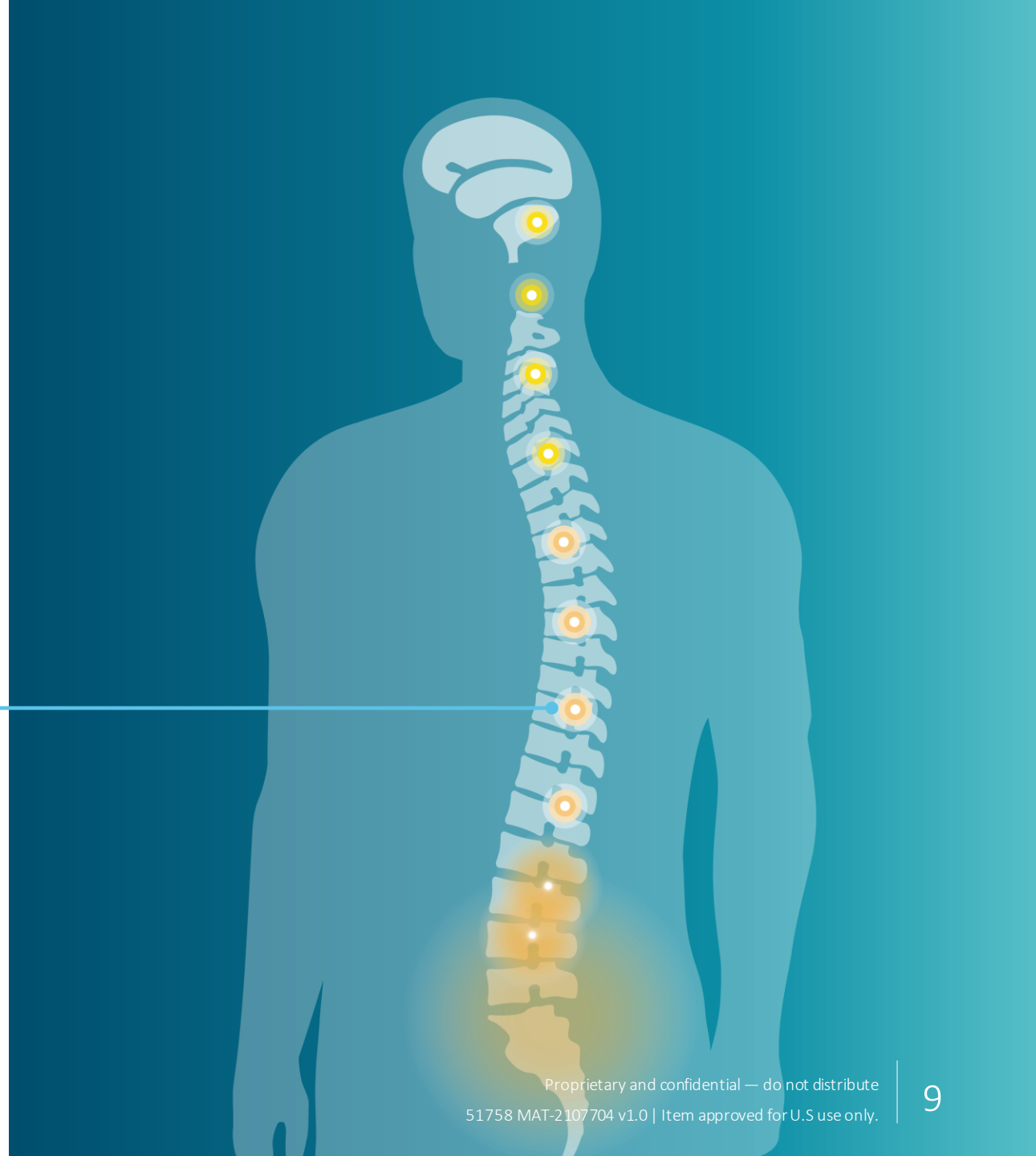
Neurostimulation, including Proclaim™ DRG Therapy may be recommended when other therapy options have failed

NEUROSTIMULATION

DRG THERAPY

NEUROSTIMULATION THERAPY

- Spinal cord stimulation (SCS) is a well-established therapy, recommended by doctors for **more than 50 years**[10]
- Worldwide, approximately **34,000** patients undergo SCS each year[11]
- Uses **mild electrical pulses to change pain signals** as they travel from the spinal cord to the brain
- May help to reduce pain to a manageable level and to return to a more normal lifestyle



TARGETED RELIEF. AT THE SOURCE.

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NEUROSTIMULATION FOR CRPS AND CAUSALGIA

Initial research showed that traditional SCS showed minor improvements for patients with CRPS[12].

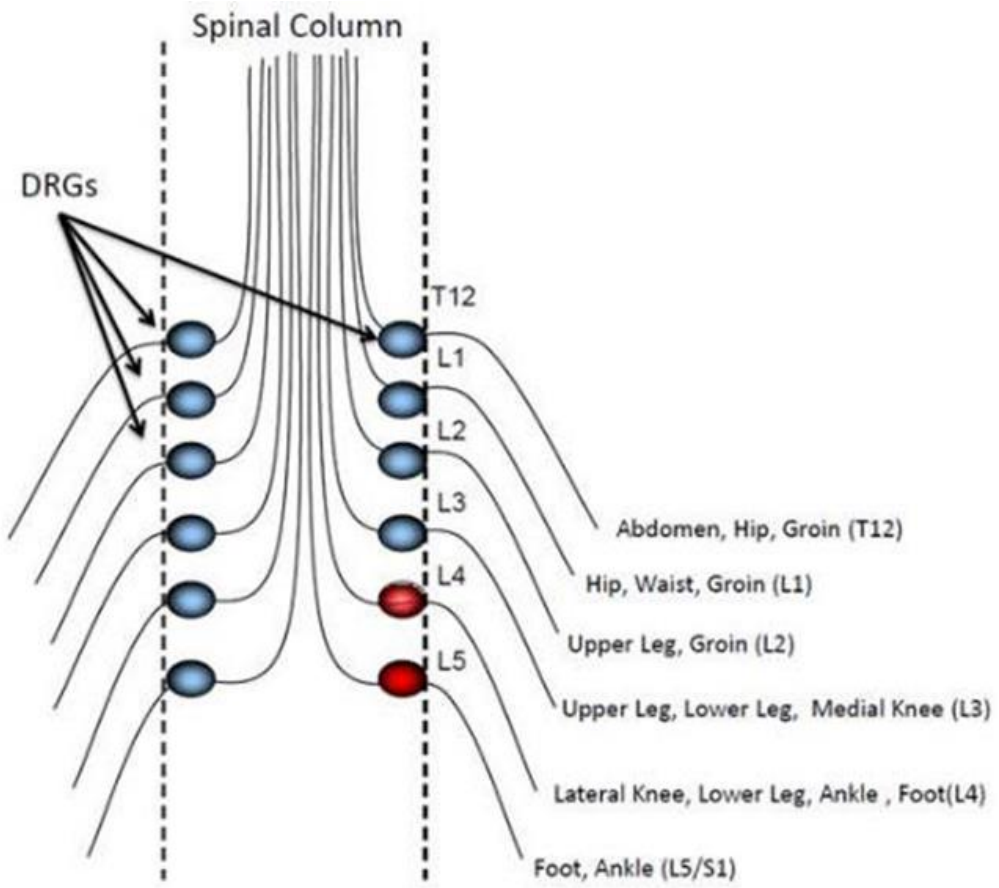
Alternatively, by stimulating the DRG, patients are able to achieve therapeutic coverage and pain relief in difficult-to-treat focal chronic intractable pain conditions[12].

TARGETED RELIEF. AT THE SOURCE.

A DIFFERENT APPROACH: STIMULATING THE DRG

1. Everyone has clusters of nerve cells along their spine called **Dorsal Root Ganglion (DRG)**

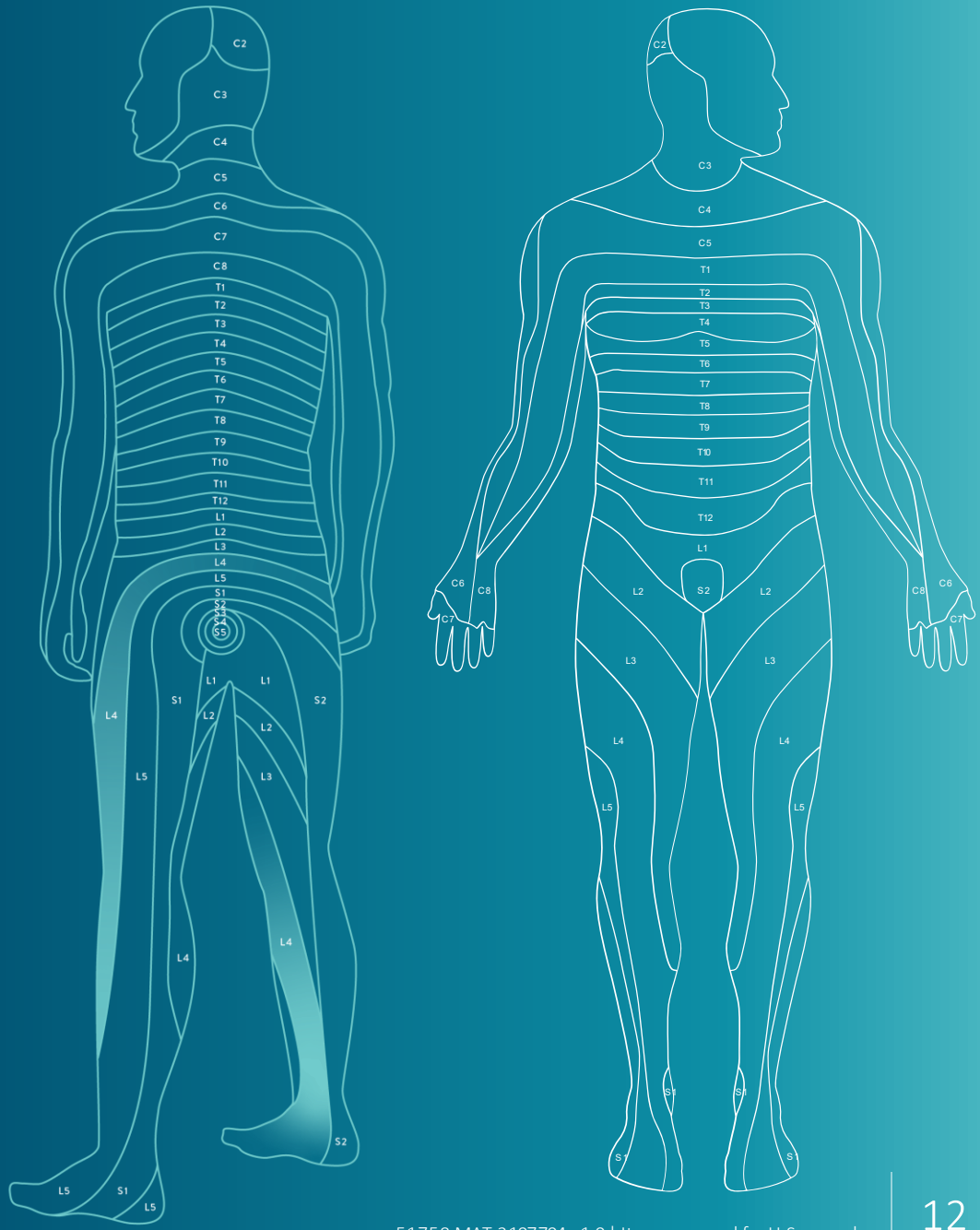
2. **DRG** nerves control pain signals from specific areas of the body where someone experiences pain



A DIFFERENT APPROACH: STIMULATING THE DRG

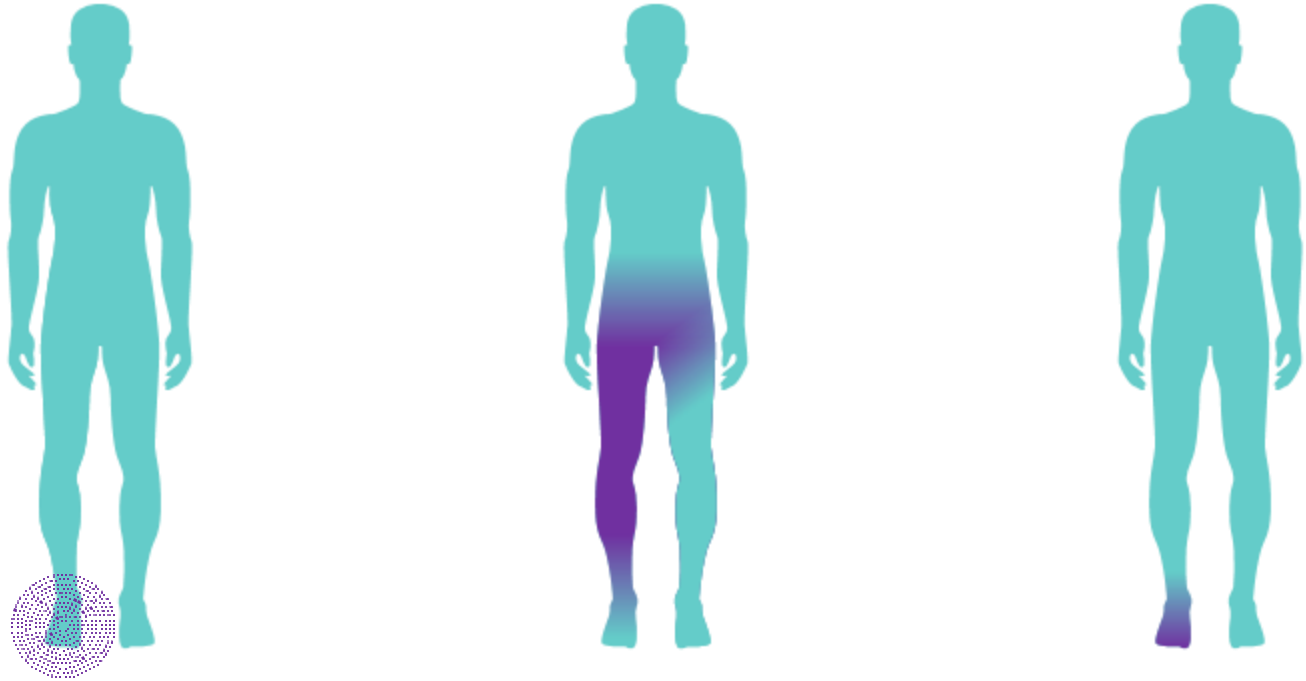
3 **DRG therapy** is a form of neurostimulation where the mild electrical signals target specific DRGs that are involved in a person's localized pain[12].

4 **DRG therapy** is designed to target difficult-to-treat chronic pain in specific areas of the lower body – such as the pelvis, groin, hip, knee, ankle, and foot – in adults with CRPS and causalgia[13]



A DIFFERENT APPROACH: STIMULATING THE DRG

5 Proclaim™ DRG Therapy has the unique ability to help manage chronic pain in targeted parts of the lower extremities due to CRPS and causalgia[13].



AREA OF PAIN

STIMULATION WITH
CONVENTIONAL TONIC SCS

STIMULATION WITH
PROCLAIM™ DRG THERAPY

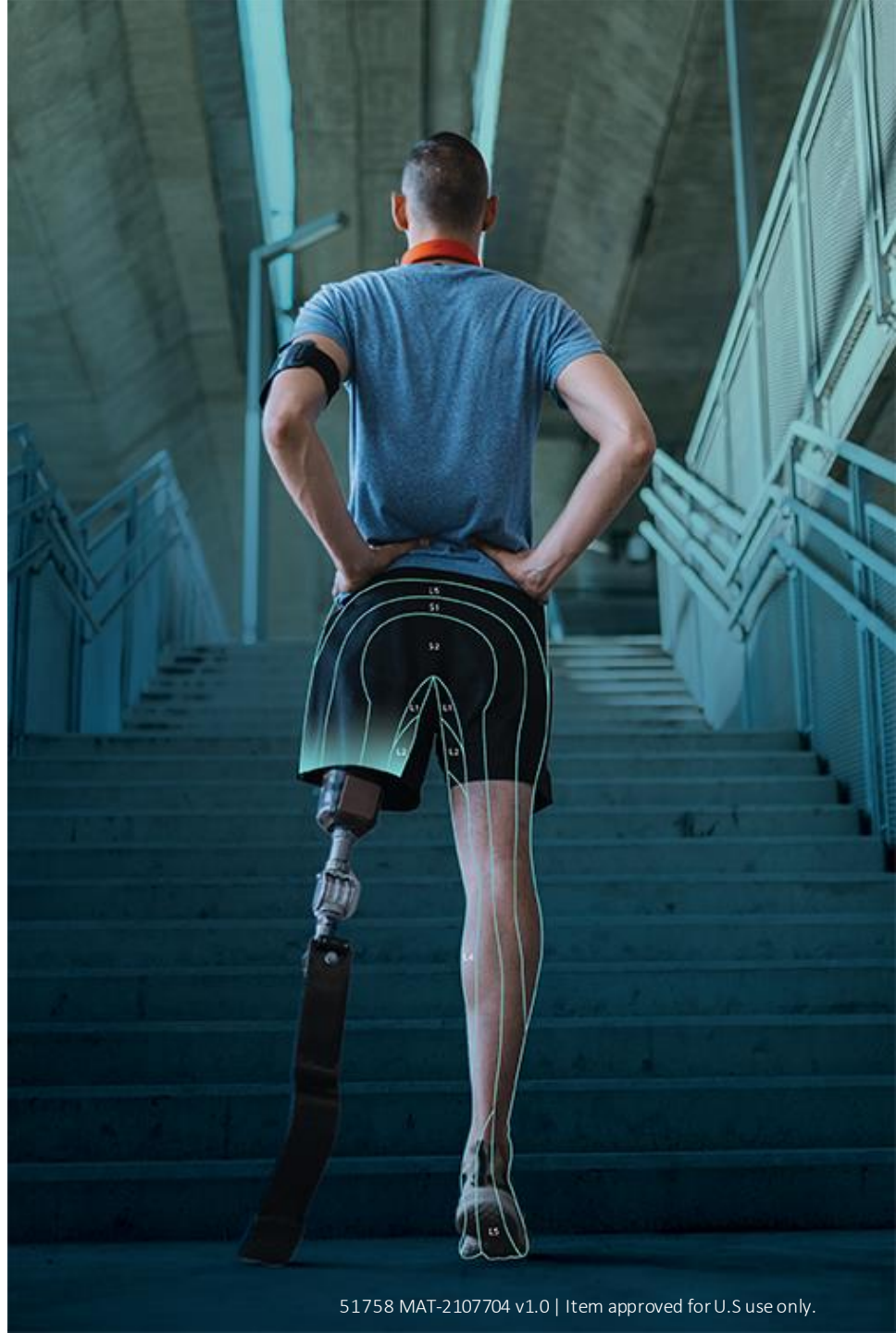
PROVEN TO PROVIDE SUPERIOR* AND LONG-TERM PAIN RELIEF[12]

ABBOTT'S DRG THERAPY:

- Has been proven safe and effective in the largest neurostimulation trial for the treatment of CRPS and causalgia[12]
- Has been studied in over 18 studies over 7 years[12,14-30]
- Can be trialed before committing to another surgery
- Eliminates the tingling sensation felt with traditional neurostimulation[12]

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

TARGETED RELIEF. AT THE SOURCE.



PROVEN TO PROVIDE SUPERIOR* AND LONG-TERM PAIN RELIEF[12]

REDUCE PAIN
an average of

81.4%

At 12 months[12]

PROVIDES PERSISTENT
pain relief to

86% OF PATIENTS

At 12 months[12]

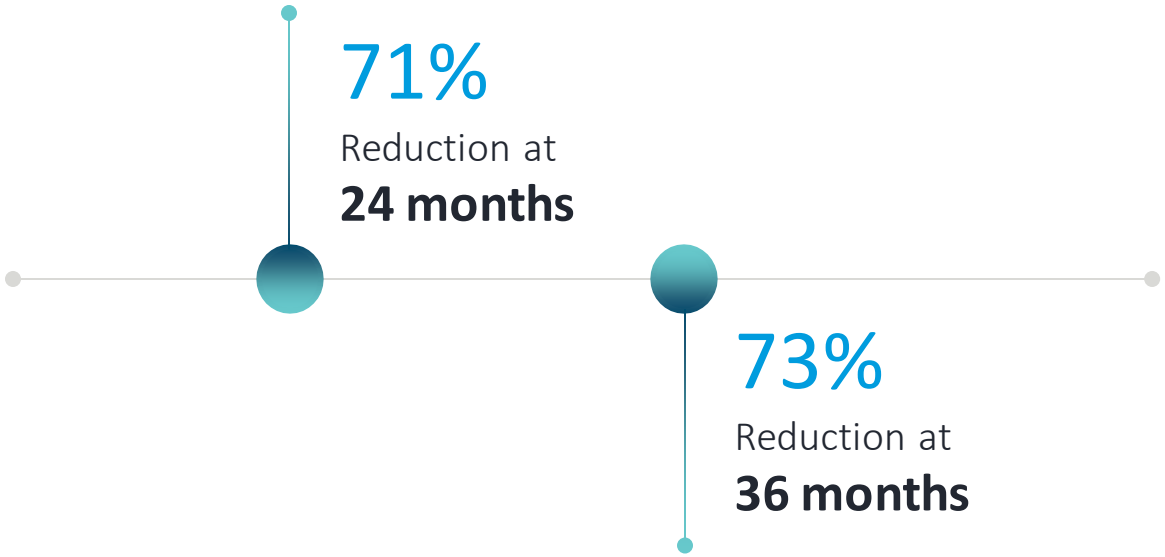
MORE THAN 8 OUT OF 10
PEOPLE

EXPERIENCED SIGNIFICANT PAIN RELIEF
AT 12 MONTHS[12]

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

RETROSPECTIVE CHART REVIEW SHOWED SIGNIFICANT PAIN RELIEF OVER 3 YEARS[31]

A retrospective chart review of 21 patients who underwent DRG stimulation showed sustained pain relief through 3-years:



Mental and physical function showed immediate and sustained improvements[31]

IMPROVES QUALITY OF LIFE** AND THE ABILITY TO PERFORM EVERYDAY ACTIVITIES[12]

Examples of Quality of Life Improvements[12]:

- Physical Function
- Social Function
- General Health

Note: Clinical significance is the practical importance of an effect (e.g. a reduction in symptoms); whether it has a real genuine, palpable, noticeable effect on daily life

**The Short-Form (SF-36) dimensions listed above are descriptive endpoints observed in the ACCURATE study. SF-36 is a self-reported health-related quality-of-life scale with 36 questions that yields scores on 8 dimensions of quality of life.

RETROSPECTIVE CHART REVIEW SHOWED SUSTAINED QUALITY OF LIFE IMPROVEMENTS[31]

A retrospective chart review of 21 patients who underwent DRG stimulation showed sustained quality of life improvements through 3-years

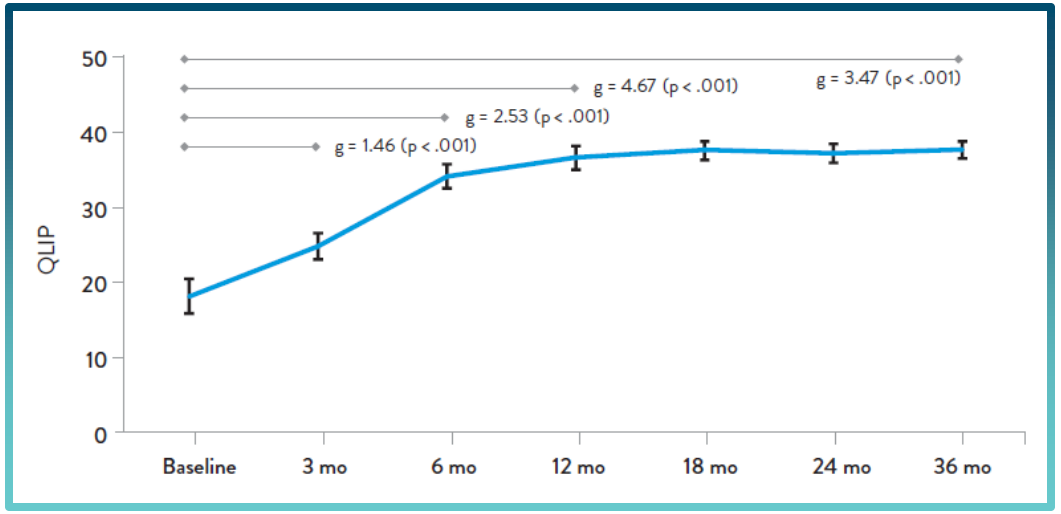
- QLIP (Quality of Life Impairment by Pain Inventory) scores:
  - Range from 0 to 40 points with 40 – least affected
  - A score of ≤ 20 points indicates severe impairment
- Both physical and mental component summary scale improved significant

Mean QLIP Scores:

18.1
Baseline

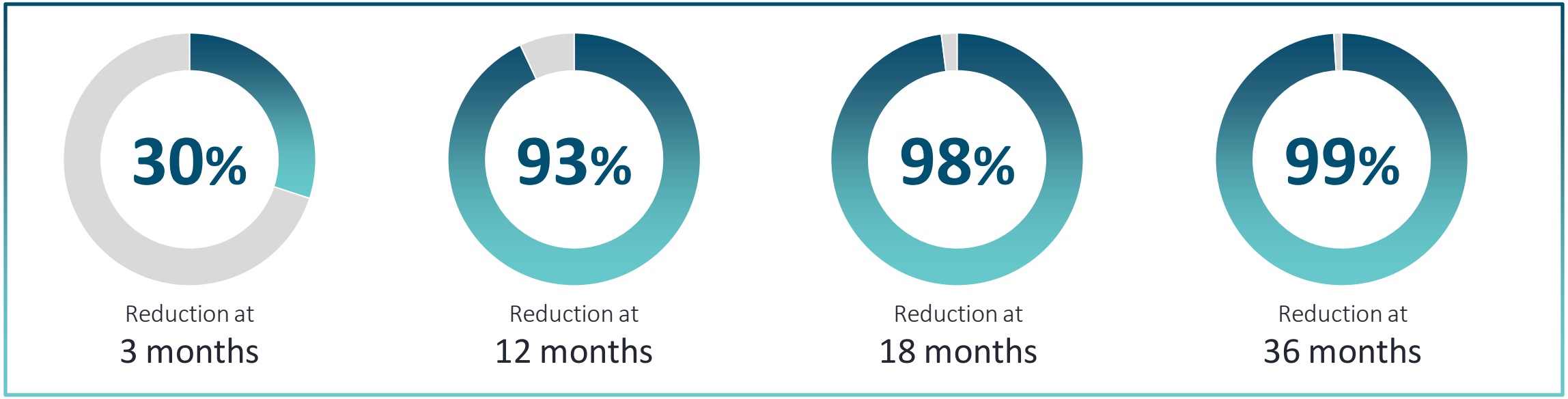
33.8
at 6-months

36.5
at 12-months



RETROSPECTIVE CHART REVIEW SHOWED SIGNIFICANT OPIOID REDUCTION[31]

A retrospective chart review of 21 patients who underwent DRG stimulation showed that opioid dosage reduced significantly over 36 months



20 out of 21 patients were completely opioid-free after 36 months.

TARGETED RELIEF. AT THE SOURCE.

PROCLAIM™ DRG NEUROSTIMULATION SYSTEM

DESIGNED TO TREAT PATIENTS WHO SUFFER FROM CRPS AND CAUSALGIA[13]

The only FDA approved DRG technology

Approved to treat CRPS and causalgia of the lower extremities[13].

HASSLE-FREE PAIN RELIEF

LOW-ENERGY SUPERIOR* THERAPY[12]

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

RECHARGE-FREE[13]

The Proclaim™ DRG Neurostimulation System gives you hassle-free pain relief with a battery that lasts 6.5 years†† on nominal settings without ever needing to charge the system.

*When compared to traditional tonic SCS based on outcomes from the ACCURATE investigational device exemption study.
††Dual-lead system with one-year shelf life at 1600-ohms impedance and 24 hours of 20-H.
Note: Hassle-free means recharge-free.

TARGETED RELIEF. AT THE SOURCE.

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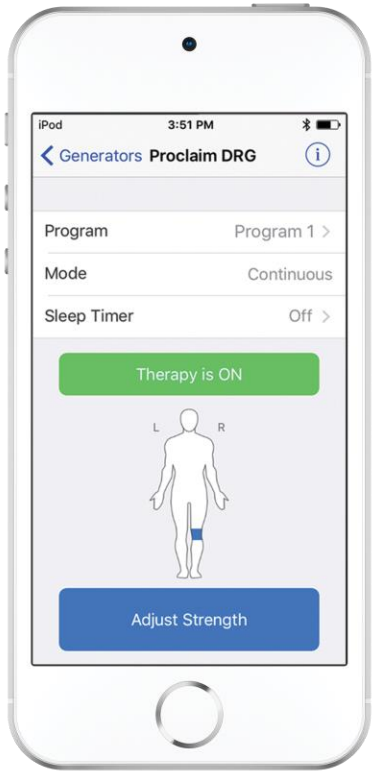
LIFE-CHANGING TECHNOLOGY AT YOUR FINGERTIPS



FAMILIAR TECHNOLOGY[13]

Control your system with Apple‡ digital devices and Bluetooth® wireless technology

FUTURE READY[13]

Features upgradeable technology that can deliver the latest advancements via software updates

MRI READY[13]

Allows scanning with a wide variety of medical imaging techniques, including magnetic resonance imaging (MRI).**

**Within approved parameters. Refer to the Instructions for Use for full details on the MR conditional scan parameters.

COMPLIMENTING THERAPY WITH DIGITAL TOOLS

NeuroSphere™ Digital Care

Patients are Taking More Control of Their Health

TECHNOLOGY USE

Chronic pain patients use smartphones to manage some aspects of their health[32]

45%

use smartphones for health purposes

21%

use personal health websites/apps

23%

use wearables

32. 2020 Brand Symbol Remote Care Patient Survey (v1.0). July 2020. n=100

Patients are Taking More Control and Telehealth Preference is at an All Time High

TELEHEALTH PREFERENCE

COVID-19 has fundamentally changed the delivery of healthcare, increasing demand and utilization of telehealth

51%

of chronic pain patients prefer telehealth appointments[32]

85%

of chronic pain patients would have chosen a device with remote programming capabilities if it had been available (over their current option)[32]

32. 2020 Brand Symbol Remote Care Patient Survey (v1.0). July 2020. n=100

NeuroSphere™ Digital Care
Only From Abbott

A connected care management platform offering powerful, intuitive digital health tools that enhance stimulation therapy management.

MYPATH™ DIGITAL HEALTH APP: Provides pre-trial education and helps manage trial

VIRTUAL CLINIC: Remote neurostimulation programming and telehealth services

PATIENT CONTROLLER APP: Direct access to therapy from personal mobile devices*

*For a list of compatible devices: https://www.neuromodulation.abbott/us/en/mobile-device-os-compatibility.html

NeuroSphere™ myPath™ Digital Health App

THERAPY EXPLORATION
Free download helps you get questions answered and stay connected

MOBILE APP EDUCATION FOR THERAPY CANDIDATES
Digital health app creates additional touchpoint for those who are considering an SCS or DRG trial

THERAPY INSIGHTS
Daily therapy insights to keep track of pain relief and functional improvements during the trial

SHAREABLE SUMMARY REPORTS
Physicians have instant access to patient-reported outcomes which can help track therapy progress during the trial experience

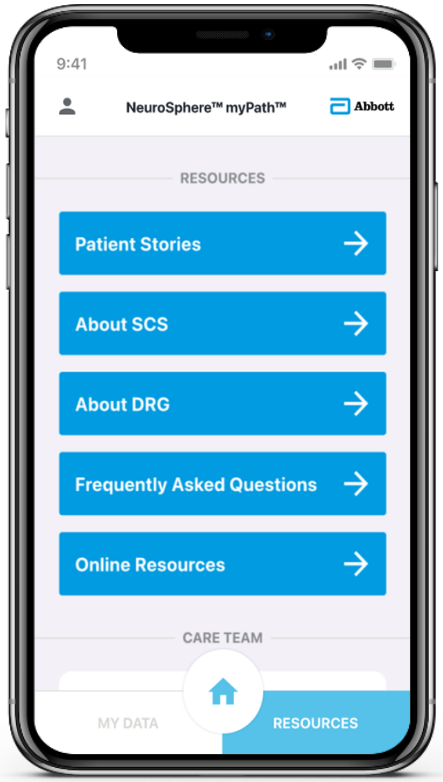
NeuroSphere™ myPath™ Digital Health App Overview

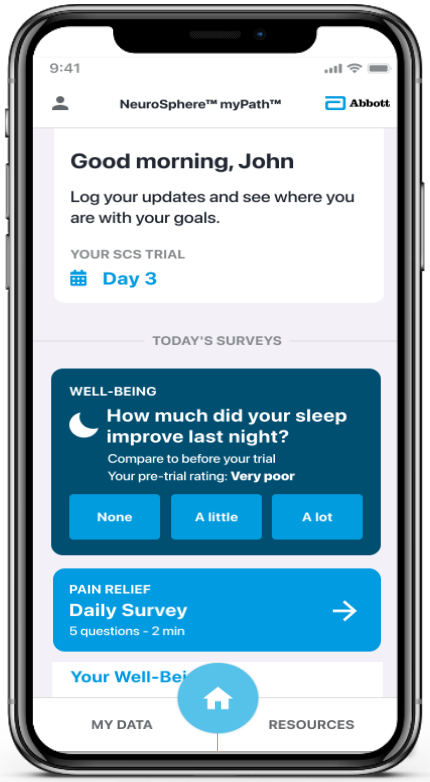
EDUCATE
Access educational resources

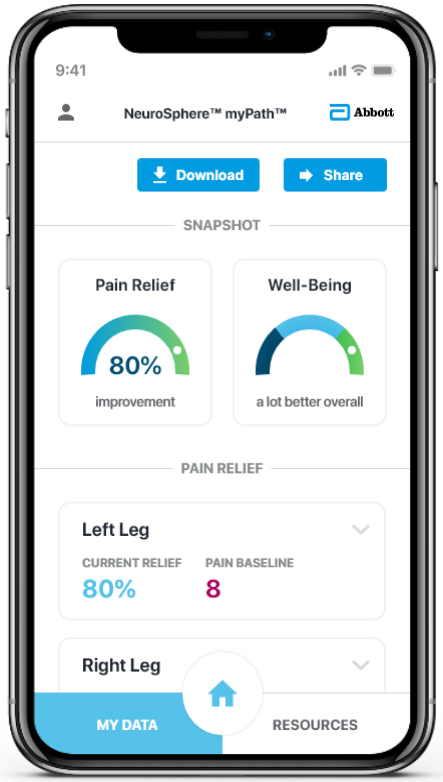
ENGAGE
Receive daily surveys and insights

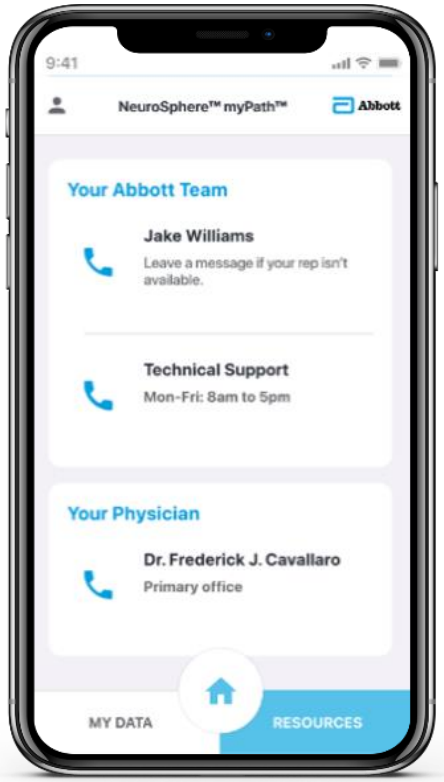
SIMPLIFY
Summarize progress and track outcomes

OUTREACH
Contact local team for additional support









NeuroSphere™ Virtual Clinic

The True Remote Programming Solution

NeuroSphere™ Virtual Clinic

CONNECTED

Connect with your doctor using in-app video chat for telehealth sessions and programming adjustments in real time without having to visit the clinic

OPTIMIZED

Virtual programming adjustments make it easier for your doctor to optimize your therapy management

PERSONALIZED

- A safe and socially distanced way to meet with your doctor for programming adjustments and follow-up visits
- More flexibility choosing the follow-up visit location and time that works best for you
- Have confidence in your care with enhanced cybersecurity controls, including double encryption and patient-authorized sessions, for secure connection

The Abbott Patient Controller App
Now Offers Personalized Access to Therapy

Using Bluetooth® wireless technology, patients can access Abbott's proprietary Patient Controller app on personal smartphones.*

*For a list of compatible devices: https://www.neuromodulation.abbott/us/en/mobile-device-os-compatibility.html

GETTING STARTED

STEPS TO GETTING PROCLAIM™ DRG THERAPY

Steps to Getting Proclaim™ DRG Therapy

1. Talk to a DRG Physician
2. Temporary Evaluation of Therapy
3. Moving Forward With the Implanted System

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#1: Talk to Your Pain Management Specialist

TAKE THE FIRST STEP

- Your doctor will determine whether you are a candidate for DRG therapy
- Your Abbott representative can help answer any additional questions

A TRIAL SYSTEM CAN HELP YOU AND YOUR DOCTOR DETERMINE HOW WELL THE THERAPY WILL WORK FOR YOU

FIND A PAIN SPECIALIST

- Find a specialist in your area who is familiar with advanced treatment options for chronic pain by scanning the QR Code

SCAN ME

#2: Temporary Evaluation

Evaluations typically last 5 to 7 days

- During the trial, you can see how well the therapy controls your pain before committing to an implanted system

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. Be sure to talk to your doctor about the risks associated with the placement of a neurostimulation system.[13]

DURING THE TRIAL, YOU CAN ASSESS WHETHER THE THERAPY:

- ☑ Provides meaningful pain relief (>50% pain relief)
- ☑ Improves your ability to perform daily activities (walking, standing, sitting)
- ☑ Improves your sleeping habits

#2: Temporary Evaluation

- A short procedure will be performed at your doctor's office, a hospital or a day surgery center
- Your doctor will place temporary leads and connect them to a small external battery
- Your Abbott representative will program your system under your doctor's guidance

AFTER THE TRIAL, YOU AND YOUR DOCTOR WILL DECIDE WHETHER THE THERAPY IS RIGHT FOR YOU.

#3: Implanted System

- The Proclaim™ DRG Neurostimulation System will be implanted in a surgical procedure, usually on an outpatient basis
- The three basic components of the implanted system are similar to the temporary system

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,[13] that is connected to the leads

PATIENT CONTROLLER

An Apple iPod‡ that enables you to adjust the therapy

Getting DRG Therapy
You Are Not Alone

HERE TO HELP

Find a DRG trained physician at DRGspecialist.com or by scanning the QR code

SCAN ME

ONLINE RESOURCES

Learn more about DRG Therapy at AboutYourPain.com

SCAN ME

FACEBOOK‡ COMMUNITY

Join our community @AbbottChronicPain to find inspiring stories, helpful tools and timely events

LEARN MORE

Q&A

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

WILL NEUROSTIMULATION CURE MY PAIN?

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

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.

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

WHAT IS THE DIFFERENCE BETWEEN TRADITIONAL NEUROSTIMULATION AND THE PROCLAIM™ DRG NEUROSTIMULATION SYSTEM?

With traditional neurostimulation, a small device is used to interrupt pain signals before they reach the brain. The painful feeling is replaced with a different feeling, which some describe as a tingling or massaging sensation, which might not be limited to the area of pain.

Alternatively, by focusing electrical stimulation specifically on the DRG, Proclaim™ DRG Therapy is able to interrupt pain signals before they reach the spinal cord or brain, so you don't feel pain in the same way. Interrupting these pain signals at the source enables the use of low energy levels and helps eliminate unnecessary stimulation throughout the body.[12] Additionally, by targeting specific DRGs, Proclaim™ DRG therapy has the unique ability to help manage lower extremity pain in targeted parts of the body where pain occurs.

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

HOW DO I KNOW THAT DRG STIMULATION WORKS?

DRG therapy was studied in the largest, randomized, head-to-head, controlled neurostimulation trial for the treatment of CRPS and causalgia. After more than a year, the results showed DRG stimulation is the best neurostimulation option for this type of pain.[11]

In diverse clinical settings around the world, Abbott's DRG technology has been studied in 18+ studies over 7+ years, proving its superiority and sustainability.[12,14-30]

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

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, stretching, and lifting you do for at least six weeks after surgery[13]. 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.[13] Be sure to ask your doctor for a complete list of restrictions.

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

WILL MY INSURANCE COVER THE TEMPORARY AND IMPLANTED 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.

THANK YOU

REFERENCES

MRI	magnetic resonance imaging	RF	radio frequency	WHO	World Health Organization
NSAID	nonsteroidal anti-inflammatory drugs	SCS	spinal cord stimulation		
OTC	over-the-counter	TENS	transcutaneous electrical nerve stimulation		

* When compared to traditional tonic SCS stimulation.

**Within approved parameters. Refer to the Instructions for Use for full details on the MR conditional scan parameters.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third party trademark, which is property of its respective owner.

†† 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.

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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. The system is intended to be used with leads and associated extensions that are compatible with the system.

Indications for Use:

US: 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 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).

International: Management of chronic intractable pain.

Contraindications:

US: 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 are contraindicated to proceed to the permanent implant procedure.

International: Patients who are unable to operate the system, are poor surgical risks, are pregnant, or under the age of 18.

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 and equipment, pediatric use, pregnancy, and case damage.

Adverse Effects: Unpleasant sensations, undesirable 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..

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