
Abbott
NEUROSTIMULATION SYSTEMS
REGAIN YOUR FREEDOM
FROM CHRONIC FOOT PAIN

TYPES OF CHRONIC FOOT PAIN

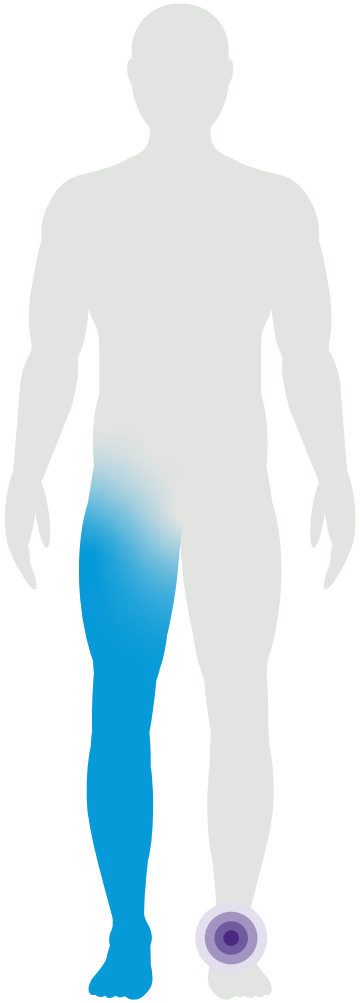
CHRONIC FOOT PAIN CAN IMPAIR YOUR MOBILITY AND BALANCE AND PUTS YOU AT A GREATER RISK FOR FALLS.[10] HEALTH CONDITIONS THAT CAN RESULT IN CHRONIC FOOT PAIN CONDITIONS INCLUDE:

DIABETIC PERIPHERAL NEUROPATHY (DPN)

Roughly one in five people living with diabetes will develop DPN,[11] a long-term complication that can cause numbness, tingling, burning or stabbing sensations in the feet.

BROAD PAIN

Nerve damage can not only affect the injured site but also multiple areas surrounding it, and may have different causes such as nerve pain from an injury or inflammation. As pain evolves over time, 88% of chronic pain patients often have two or more distinct painful areas.[12]



COMPLEX REGIONAL PAIN SYNDROME (CRPS)

CRPS is a form of chronic pain that usually affects a leg and is often out of proportion to the severity of the injury or disease. CRPS typically develops after an injury, surgery, stroke, heart attack or unknown cause.

TRAUMATIC FOOT/ANKLE INJURY OR SURGICAL NERVE INJURY (CAUSALGIA)

Causalgia is described as a long-lasting, intense pain caused by nerve damage after an injury, trauma or surgery or following amputation.

CHRONIC PAIN IS A COMMON CONDITION

One in three American adults suffer from chronic pain.[1] Chronic pain can be intermittent or constant and can spread beyond the site of the injury as well as increase in intensity as time passes.

Chronic pain is either mechanical or neuropathic. Mechanical pain has a known cause, such as breaking a bone, while neuropathic pain can occur with or without a specific reason or as a result of a diagnosis like diabetes.

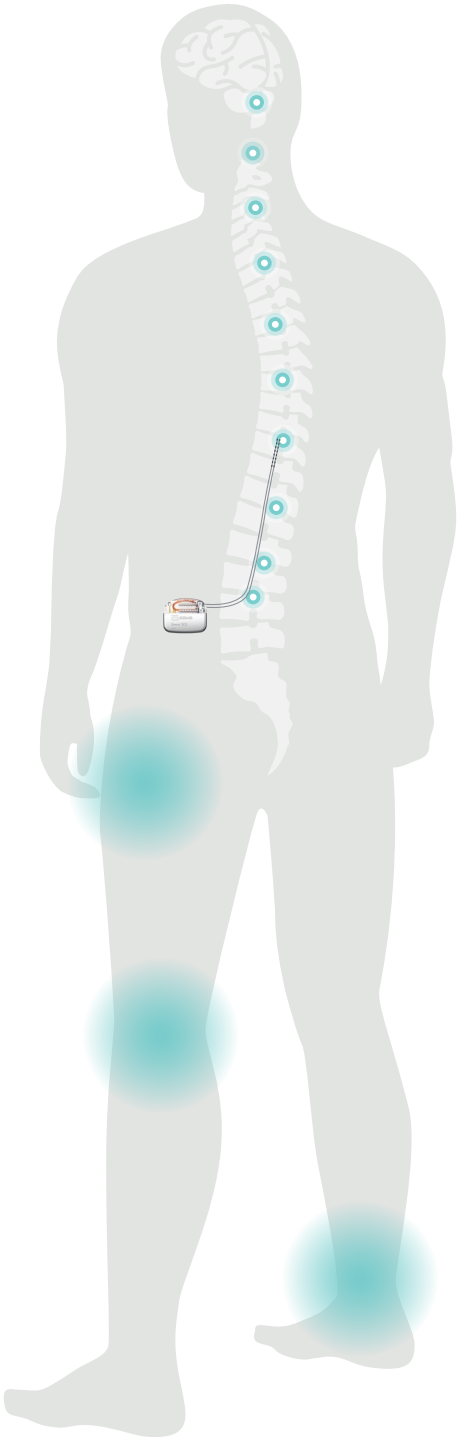
TINGLING BURNING NUMBNESS

Neuropathic pain can occur whether sitting, standing or lying down, and the pain is often described as tingling, burning, shooting, stabbing, prickling or sharp. Medication does not always relieve neuropathic pain.

Pain that affects a large anatomical area — for example, in the low back and legs — is called broad pain. Pain in one specific area, such as in the foot, is called focal pain.

Chronic foot pain can be particularly bothersome because the foot plays an essential role in all weight-bearing activities and helps with balance, shock absorption and mobility.[2]

DISCOVER THE RIGHT THERAPY



Neurostimulation is an option for chronic pain that has been used for more than 50 years. It has been proven effective in managing pain and demonstrated reduced or sustained intake of pain medication.[3,4]*

Neurostimulation therapy works by stimulating nerves along the spine or the dorsal root ganglion (DRG) using controlled electrical pulses to interfere with pain signals and alleviate pain.[5]

Patients with diabetic peripheral neuropathy (DPN) using neurostimulation therapy are **18 times more likely** to obtain pain relief than with conventional medical management.[6]**,***

Our neurostimulation therapies include DRG stimulation for focal pain relief, only available from Abbott, and spinal cord stimulation (SCS) for broad pain relief.

NEUROSTIMULATION COULD HELP

THE THERAPY CONSISTS OF THREE MAIN COMPONENTS.[7-9]

LEADS

Thin wires that deliver electrical pulses from the battery to nerves along the spine or to the DRG.

BATTERY

A small device that is connected to the leads to supply power.

PATIENT CONTROLLER

An iOS[‡] software-compatible app[†] that enables you to adjust your therapy within prescribed limits.

One of the benefits of these therapies is you can ***trial the system first*** *using an external battery to see if it provides meaningful relief before moving forward with a permanent implant.*

SCAN THE QR CODE

for more information or to learn whether neurostimulation may be able to help your chronic foot pain.

*Observed as part of an additional analysis in ACCURATE.

**The BurstDR™ stimulation mode has not been evaluated for effectiveness in the diabetic peripheral neuropathy (DPN) population.

***Combined data from comparative studies in the Abbott Clinical Summaries IFU. Analysis of all randomized subjects in an intent-to-treat approach.

†Available on eligible Apple‡ mobile digital devices. For a full list of personal Apple mobile digital devices compatible with the Patient Controller app from Abbott, visit http://www.NMmobiledevicesync.com/cp.

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3. Deer T, Slavin KV, Amirdelfan K, et al. Success using neuromodulation with BURST (SUNBURST) study: results from a prospective, randomized controlled trial using a novel burst waveform. *Neuromodulation*. 2018;21(1):56-66. doi:10.1111/ner.12698
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5. North American Neuromodulation Society. Our therapies. Accessed June 7, 2023. https://neuromodulation.org/Education/OurTherapies.aspx
6. Abbott. Data on File. DPN Pain Relief Comparison Memo (MAT-2308037). 2023.
7. Abbott. Proclaim™ SCS Implantable Pulse Generator Clinician's Manual. 2023.
8. Abbott. Eterna™ SCS Implantable Pulse Generator Clinician's Manual. 2023.
9. Abbott. Proclaim™ DRG Implantable Pulse Generator Clinician's Manual. 2018.
10. Hawke F, Burns J. Understanding the nature and mechanism of foot pain. *J Foot Ankle Res*. 2009;2:1. doi:10.1186/1757-1146-2-1
11. Martin CL, Albers JW, Pop-Busui R; DCCT/EDIC Research Group. Neuropathy and related findings in the diabetes control and complications trial/epidemiology of diabetes interventions and complications study. *Diabetes Care*. 2014;37(1):31-38. doi:10.2337/dc13-2114
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Risk Information: The placement of a neurostimulation system requires surgery, which exposes patients to certain risks. Complications such as infection, swelling, bruising, and possibly the loss of strength or use in an affected limb or muscle group (e.g., paralysis) are possible. Additional risks such as undesirable changes in stimulation may occur over time. Be sure to talk to your doctor about the possible risks associated with neurostimulation.

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Rx Only

Brief Summary: Prior to using Abbott 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.

SCS Indications for Use: Spinal Cord Stimulation is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, nonsurgical back pain (without prior surgery and not a candidate for back surgery), and diabetic peripheral neuropathy of the lower extremities.

Contraindications: This system is contraindicated for patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

Warnings: Poor surgical risks, magnetic resonance imaging (MRI), diathermy therapy, electrosurgery, implanted cardiac systems or other active implanted devices, interference with other devices, operation of machinery, equipment and vehicles, explosive and flammable gases, keep the device dry, pediatric use, pregnancy and nursing, use in patients with Diabetes, Stimulation mode, device components, device modification, application modification, case damage, generator disposal, product materials. Patients who are poor surgical risks, with multiple illnesses, or with active general infections should not be implanted.

Precautions: Clinician training, patient selection, infection, implantation of two systems, implantation of multiple leads, implant heating, high stimulation outputs, electromagnetic interference (EMI), consumer goods and electronic devices, lead movement, patient training, programmer use, single-use, sterile device, storage environment, expiration date, recharge-by date, handle devices with care, care and handling of components, package or component damage, exposure to body fluids or saline, system testing, high-output ultrasonics and lithotripsy, ultrasonic scanning equipment, external defibrillators, therapeutic radiation, security, antitheft, and radio frequency identification (RFID) devices, scuba diving or hyperbaric chambers, wireless use restrictions.

Adverse Effects: Unpleasant sensations or motor disturbances, undesirable changes in stimulation, stimulation in unwanted places, lead migration, epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of a lead in the epidural space, cerebrospinal fluid leakage, paralysis, weakness, clumsiness, numbness, or pain below the level of the implant, persistent pain at the electrode or IPG site, seroma at IPG site, allergic or rejection response to implant materials, implant migration or skin erosion around the implant, battery failure, change in blood glucose levels in response to any side effect. User's Guide must be reviewed for detailed disclosure.

DRG 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 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).

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, 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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