BURSTDR™ STIMULATION FOR CHRONIC PAIN

PAIN INTER-RUPTED

LIFE TRANSFORMED

ST. JUDE MEDICAL™

▲ **Sam B,** 18 months after implant and able to keep things shipshape on the waters of San Francisco Bay.

IMAGINE YOUR LIFE TRANSFORMED

Chronic pain is a heavy burden that consumes and limits your life. The long journey from one failed back surgery to the next. Medications that do too little to numb the pain and too much to numb the patient. Every day, pain takes its toll on you mentally and physically; turning you from participant to spectator in your own life.

If you or a loved one would like to experience a life transformed then it may be time to consider the latest advancement in neurostimulation therapy: **BurstDR™ stimulation* from St. Jude Medical.**

For patient stories and videos, visit:

PowerOverYourPain.com

BURSTDR™ STIMULATION

Relief from **EMOTIONAL SUFFERING**†[1,2]

Relief from **PHYSICAL PAIN**[1,2]

†Pain and suffering as measured by VAS.

IT'S TIME FOR SOMETHING DIFFERENT.

Neurostimulation also called spinal cord stimulation or SCS, has been recommended by doctors for over 40 years to manage chronic pain in the back, arms or legs.

BurstDR™ stimulation is a new form of neurostimulation therapy. By understanding how the brain naturally manages pain, doctors created a new therapy that works by mimicking natural patterns found in the brain.[3] This therapy is believed to address both physical pain and the way it affects you emotionally.[3]

BurstDR™ stimulation is different from the other approaches you may have tried. **The result: relief from pain and the chance to reclaim your life.**[1,2]

To learn more about BurstDR™ stimulation, exclusively from St. Jude Medical, visit

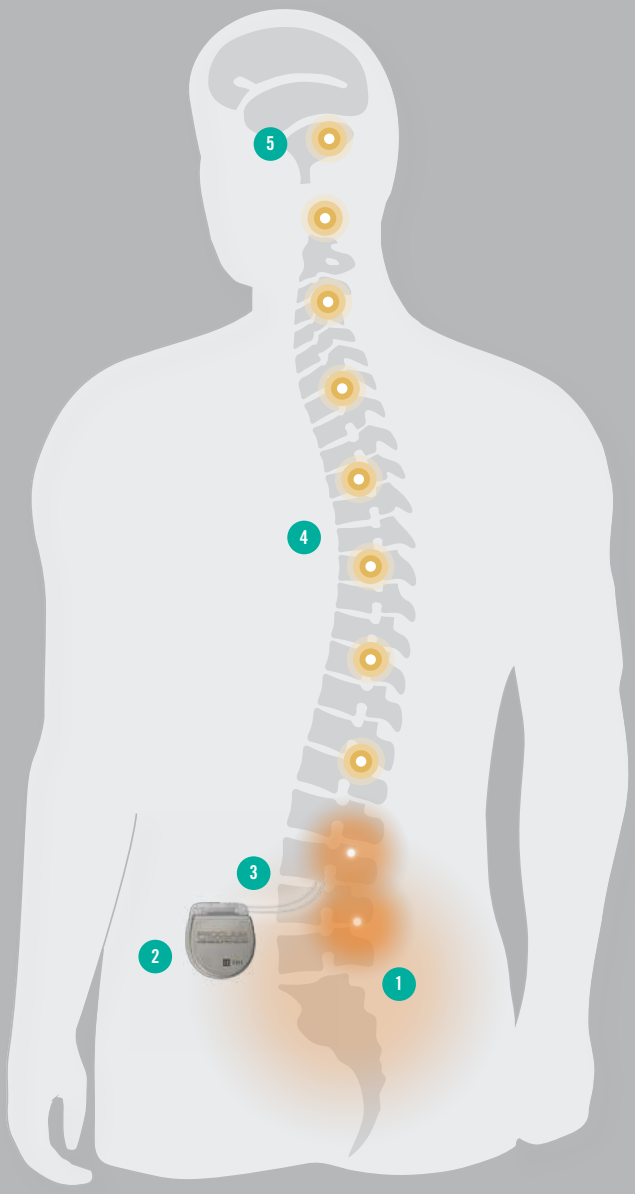
PowerOverYourPain.com

HOW BURSTDR™ STIMULATION WORKS.

When you feel chronic pain, it is because your nerves are sending pain signals to your brain. BurstDR™ stimulation works to reduce pain by altering the pain signals as they travel to the brain.[3]

1. Pain signals travel up the spinal cord to the brain.
2. A generator, similar to a cardiac pacemaker, sends BurstDR pulses to a thin wire called a lead.
3. The lead delivers these pulses to nerves along the spinal cord.
4. The pulses modify the pain signals as they travel to different parts of the brain.
5. The pulses change the way your body perceives pain—providing potential relief from the physical pain as well as the suffering† associated with the pain.[1,2]

†Pain and suffering as measured by VAS.



To watch a short video on How BurstDR™ stimulation works, visit

PowerOverYourPain.com

PROVEN SUPERIOR.

BurstDR™ stimulation has been clinically proven in numerous studies around the world to:

- **Provide superior pain relief** compared to traditional neurostimulation therapy.[1,2]
- **Reduce or eliminate the tingling sensation** felt with traditional neurostimulation.[1,2]

While neurostimulation helps most patients experience at least some reduction in pain, not everyone responds in the same way. The amount of pain relief varies with each individual. Complications related to placement and/or use of the device may occur. Be sure to discuss the risks and benefits of neurostimulation with your doctor.

PREFERRED
BY MORE PATIENTS.

Among patients studied, the majority said they preferred BurstDR™ stimulation to traditional neurostimulation.[1,2] The pain relief provided by BurstDR stimulation was also proven to improve patients' lives by:

- Improving patients' ability to perform everyday activities.[‡,1,2]
- Reducing patients' emotional suffering associated with pain.[†,1,2]

The majority of patients say they prefer BURSTDR™ STIMULATION[1,2]

†Pain and suffering as measured by VAS.

HOW DO I KNOW IF BURSTDR™ STIMULATION IS RIGHT FOR ME?

One of the benefits of neurostimulation is that you can try BurstDR™ stimulation using a temporary system, typically for three to five days, before committing to an implanted system.

Our temporary system lets you manage your therapy wirelessly using an app on an Apple™ iPod touch™ mobile digital device. The small external generator easily hides under your clothing. It's so discreet we call it the St. Jude Medical™ Invisible Trial System.

During the evaluation period you will have the opportunity to assess whether the therapy:

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

▲ The St. Jude Medical™ Invisible Trial System uses Apple™ mobile digital devices with wireless communication and offers two types of stimulation—giving you a better chance at a successful evaluation.

THE ST. JUDE MEDICAL™

INVISIBLE TRIAL SYSTEM

1 TEMPORARY LEAD

2 EXTERNAL GENERATOR

3 PATIENT CONTROLLER

To learn more about the St. Jude Medical™ Invisible Trial System, visit:

PowerOverYourPain.com

START WITH A TEMPORARY EVALUATION.

To begin, you will undergo a short procedure, often performed at a doctor's office, hospital or day surgery center. During this time:

1. Your doctor will place the temporary leads and test them to ensure they are placed correctly.
2. After testing, your doctor will connect the leads to the small external generator that will be worn outside the body, typically on your lower back.
3. In the recovery room, your St. Jude Medical representative will program your external generator under your doctor's guidance.

Using the St. Jude Medical™ Invisible Trial System, you will be able to assess how well the therapy controls your pain throughout the day and during different activities. If, at the end of the evaluation period, you and your doctor decide BurstDR™ stimulation is right for you, you can choose to have the system implanted.

WHAT ARE SOME OF THE RISKS ASSOCIATED WITH THE PROCEDURE?

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 or use in 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.

MOVING ON.
LEAVING PAIN
BEHIND.

If the evaluation period is successful, you can have the system implanted. The system is usually implanted in a surgical procedure on an outpatient basis. 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 undesirable change in stimulation. In general, you should be able to perform your daily activities with less pain over time.

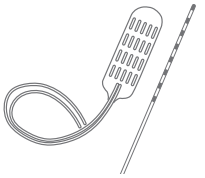
A temporary evaluation showed **Lori P.** of Sachse, TX ▶ how neurostimulation could manage the chronic pain that was making her rehabilitation impossible—all without the commitment of an implant.

▲ After receiving his St. Jude Medical™ neurostimulation system, **Jeff B.** promptly retired from his job so he could spend time riding his motorcycle, oil painting, fly fishing and taking care of his three and a half acres.

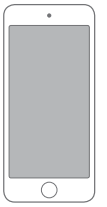
THE IMPLANTED SYSTEM.

The implanted system is similar to the temporary system with three basic components:

The generator
produces the pulses that manage your pain. It is a small device, usually implanted in the abdomen or buttock area, that is connected to the leads.



The leads
are thin wires that deliver pulses from the generator to nerves along the spinal cord. Leads are placed in an area along the spinal column called the epidural space.



The controller
is a handheld device similar to a remote control that lets you adjust the therapy.

To learn more about the St. Jude Medical™ neurostimulation systems, visit:

PowerOverYourPain.com

INNOVATION
FROM ST. JUDE MEDICAL

St. Jude Medical™ neurostimulation technologies are unique because they are developed with the patient in mind—designed to seamlessly interact with your daily activities and lifestyle.

▲ The Proclaim™ Elite Recharge-free SCS system featuring BurstDR™ stimulation offers patients Invisible Therapy™ with Apple™ iPod touch™ mobile digital device, Bluetooth® wireless technology and upgradeable technology.

Greater Chance for Success

Only St. Jude Medical™ neurostimulation systems give you access to BurstDR™ stimulation and traditional neurostimulation (also called tonic stimulation); two different stimulation options for a greater chance of success.

Familiar Consumer Technology

The St. Jude Medical™ Invisible Trial System and Proclaim™ Elite Recharge-free SCS system use Apple™ mobile digital devices and Bluetooth® wireless technology for seamless integration into a modern lifestyle.

Future Ready

Upgradeable technology means you won't need surgery to benefit from our next advancement in chronic pain therapy. Approved technologies are easily delivered via software updates.

MRI Ready

Our newest neurostimulation systems allow scanning with a wide variety of medical imaging techniques, including MRIs.*

Designed for Patient Needs

St. Jude Medical™ neurostimulation systems are available with rechargeable and recharge-free batteries. Your doctor will help you decide which is right for you based on your lifestyle and pain pattern.

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

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.

WHAT IS THE DIFFERENCE BETWEEN TRADITIONAL NEUROSTIMULATION AND BURSTDR™ STIMULATION?

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.

BurstDR™ stimulation works similarly, however the BurstDR therapy was designed to more naturally manage pain. It works by mimicking natural patterns found in the brain—modifying pain signals and changing the way your body perceives pain.[3] Most patients do not feel any sensation with BurstDR stimulation.[1,2]

While BurstDR stimulation has been shown to be preferred by more patients,[1,2] St. Jude Medical™ neurostimulation systems offer both therapies—giving you a greater chance at success.

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. 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. Be sure to ask your doctor for a complete list of restrictions.

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.

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 physician on specific medication questions.

To review more Frequently Asked Questions, visit:

PowerOverYourPain.com

▲ Since receiving his St. Jude Medical™ neurostimulation system, **Dominic B.** has been able to play superhero for his son Damien.

I'D LIKE TO LEARN MORE ABOUT ST. JUDE MEDICAL™ BURSTDR™ STIMULATION.

I have received an information kit from my doctor, and I would like to have a member of the St. Jude Medical clinical team contact me to answer my questions and/or to let me know about upcoming educational sessions.

name

address

city | state | zip

phone | email

Contact me via: phone email

Your pain management doctor

signature | date

KNOWLEDGE NEVER HURTS.

Talk to your doctor about how BurstDR™ stimulation may benefit your specific pain. For more detailed information and a short film about the experiences of patients with chronic pain, visit **PowerOverYourPain.com.**

YOUR DOCTOR THINKS THAT BURSTDR™ STIMULATION MIGHT BE RIGHT FOR YOU.

To learn more about BurstDR stimulation, complete the back of this card and return it to your doctor.

*BurstDR™ stimulation, patented technology exclusively from St. Jude Medical, is also referred to as Burst stimulation in clinical literature.

†Pain and suffering as measured by VAS.

‡Based on PGIC scores of moderately better improvement or higher.

1. St. Jude Medical™ Proclaim™ Neurostimulation System Clinician's Manual. Plano, TX. 2016.
2. St. Jude Medical™ Prodigy™ Neurostimulation System Programming and Reference Manual. Plano, TX. 2016.
3. De Ridder, D., Vanneste, S., Plazier, M., & Vancamp, T., (2015). Mimicking the Brain: Evaluation of St. Jude Medical's Prodigy Chronic Pain System with Burst Technology. *Expert Review of Medical Devices, 12*(2), 143–150.

The stories featured in this brochure explain the experiences of people who have received neurostimulation systems for the management of chronic pain of the trunk and/or limbs. These results are specific to the individuals featured. While most people experience at least some reduction in pain, the amount of pain relief experienced varies by individual. The surgical placement and/or use of a neurostimulation system poses certain risks. The occurrence of these risks also varies by individual.

Rx Only
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications for Use: Spinal cord stimulation 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 and intractable low back and leg pain. **Contraindications:** Patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation. **Warnings/Precautions:** Diathermy therapy, implanted cardiac systems, magnetic resonance imaging (MRI), explosive or flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery and equipment, postural changes, pediatric use, pregnancy, and case damage. Patients who are poor surgical risks, with multiple illnesses, or with active general infections should not be implanted. **Adverse Effects:** Painful stimulation, loss of pain relief, surgical risks (e.g., paralysis). User's Guide must be reviewed for detailed disclosure.

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