DRG THERAPY FOR CHRONIC PAIN

PAIN INTER-RUPTED

LIFE TRANSFORMED

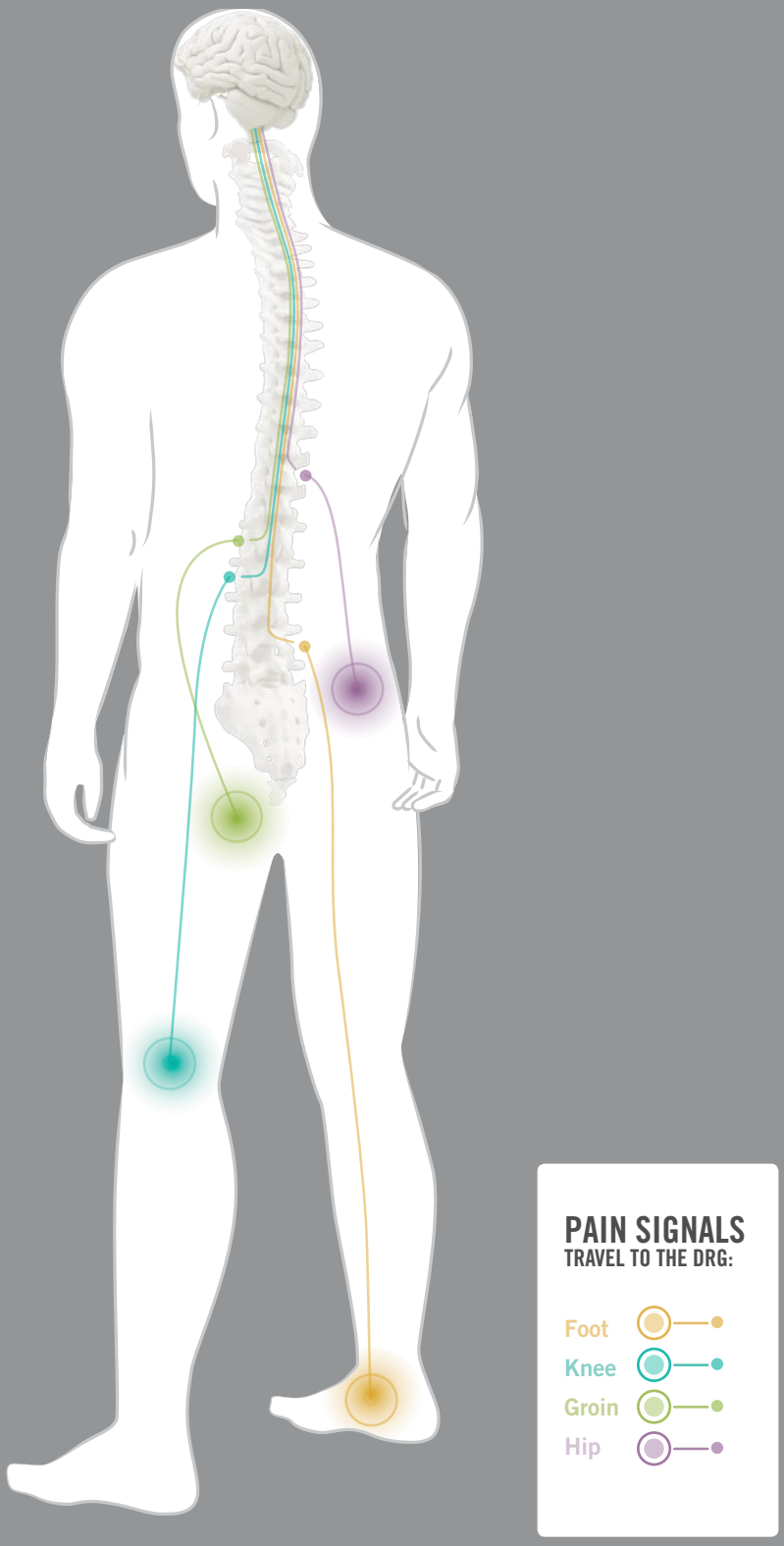
ST. JUDE MEDICAL

A DIFFERENT TYPE OF PAIN CALLS FOR A DIFFERENT APPROACH.

Chronic pain* is a common condition, affecting almost one in five adults globally.[1] But yours is different from most. You've tried the methods that work for other people, but nothing seems to help. It's well known that this kind of pain is limited to a specific area of your body. This sort of difficult-to-treat isolated chronic pain may start in a lower extremity **(foot, knee, hip, and groin)** following an injury or surgical procedure and grow worse over time.

Now imagine your life transformed. Because today, there's a unique approach to pain like yours: neurostimulation that stimulates the dorsal root ganglion—a cluster of nerve cells in the spine, also called the DRG—that directly targets the area of the body where your pain occurs. This is a new therapy using a well-studied and understood approach for addressing the type of pain you're suffering. DRG therapy is the next generation in pain relief and it's offered exclusively by St. Jude Medical.

*Chronic pain defined as pain that has been present for a minimum of six months.[2]


PAIN SIGNALS
TRAVEL TO THE DRG:
Foot
Knee
Groin
Hip

HERE'S HOW DRG THERAPY CAN HELP.

The Dorsal Root Ganglion (DRG) has been of interest to pain physicians for years. This nerve cluster acts like a traffic light, regulating signals and sensations as they travel to the brain. Stimulation of the DRG can actually modify the pain signals getting through—resulting in the reduction of pain.

For patients with pain that is limited to a specific area of the body, DRG therapy often works where other treatments may not—or provide only partial relief. That's because the DRG corresponds to specific anatomical locations in the body and relays information, such as pain signals, to the brain. Because of its unique ability to target the areas of the body where pain occurs, DRG therapy can be especially helpful for patients like you.

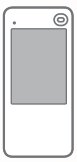

MORE THAN 300,000 PEOPLE
HAVE SUCCESSFULLY RECEIVED
NEUROSTIMULATION SYSTEMS
OVER THE PAST 40 YEARS.[4]

THE DRG SYSTEM. IT'S THIS SIMPLE.

THE DRG NEUROSTIMULATOR SYSTEM CONSISTS OF THREE COMPONENTS:

THE GENERATOR - a small device that sends out mild electrical pulses, which contains a battery. This is implanted in your body.

THE LEADS - thin insulated wires that carry the electrical pulses from the generator to your dorsal root ganglia. These are placed in your body in the area of the DRG.



THE PATIENT CONTROLLER - a handheld "remote control" that allows you to adjust the strength and location of stimulation or even turn stimulation off.

Placement of the DRG system is similar to that of other neurostimulation devices.

MAKE SURE DRG THERAPY WORKS FOR YOU. TRY IT OUT FIRST.

One of the benefits of the DRG neurostimulation system is that you can be fitted with a temporary device that works like an implanted system but can be removed. This allows you to determine its effectiveness for your pain prior to undergoing an implant. You will have a short, minimally-invasive procedure, during which you are awake and answering questions. Your doctor will:

- **Implant a few small, thin leads near your DRG.**
- **Attach the leads to a temporary generator that you can wear outside of your clothing or on your belt.**
- **Ask you to provide feedback on where you feel stimulation.**

Afterward, you will be trained to use the device and find the settings that feel best.

While you wear the temporary system you will be asked to limit physical activities that involve lifting, bending, twisting or raising your arms above your head. Otherwise, you will be able to resume daily living. Look forward to the ability to do and enjoy things, like sleeping, walking and shopping, that were once difficult. Life more like you remember it—before the pain.

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Life more like you remember it—before the pain.

DRG THERAPY WORKS!
NOW WHAT?

Now, it's time to talk to your doctor about having the system implanted.

You will need to stop the temporary stimulation briefly before the surgery to implant the generator. You'll likely be admitted to a surgery center and some of the components of the temporary system may be removed. The implant does involve a minimally-invasive surgical procedure that includes implanting the generator under your skin. It's important that you discuss with your doctor all of the complications associated with an implanted neurostimulation device and whether you are at risk.

The generator will be implanted with leads that will be placed close to the target dorsal root ganglia identified during the temporary evaluation. As with the evaluation procedure, you will be awake and answering questions. Within a few days, your system should begin working just like before.

Generator and Patient Controller

WHAT ARE THE RISKS ASSOCIATED WITH THIS PROCEDURE?

The placement of a neurostimulation system requires surgery, which exposes patients to certain risks. Complications such as infection, swelling and bruising are possible. Additional risks such as undesirable changes in stimulation may occur over time. Be sure to talk to your doctor about all the possible risks associated with neurostimulation.

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

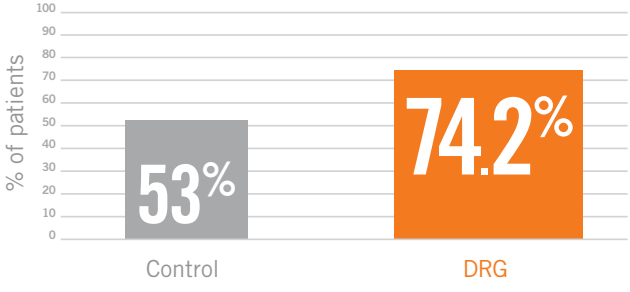
Your doctor will give you detailed information about restrictions and activities with your system. As a general rule, however, it is important to restrict the amount of bending, twisting and reaching you do for the first six to eight weeks after surgery. This is the time that the healing is taking place around the leads. There are also some permanent restrictions associated with receiving a neurostimulation system. Be sure to ask your doctor for a complete list of restrictions.

PROOF OF EFFECTIVE RELIEF FOR PATIENTS LIKE YOU.

THE LARGEST NEUROSTIMULATION CLINICAL TRIAL EVER CONDUCTED AMONG PATIENTS

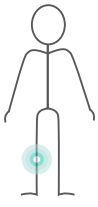
152 patients enrolled in study with chronic intractable lower limb pain typically resulting from a previous injury, the ACCURATE clinical study, showed that with DRG therapy:[3]

74.2% of DRG patients had pain relief at 12 months*

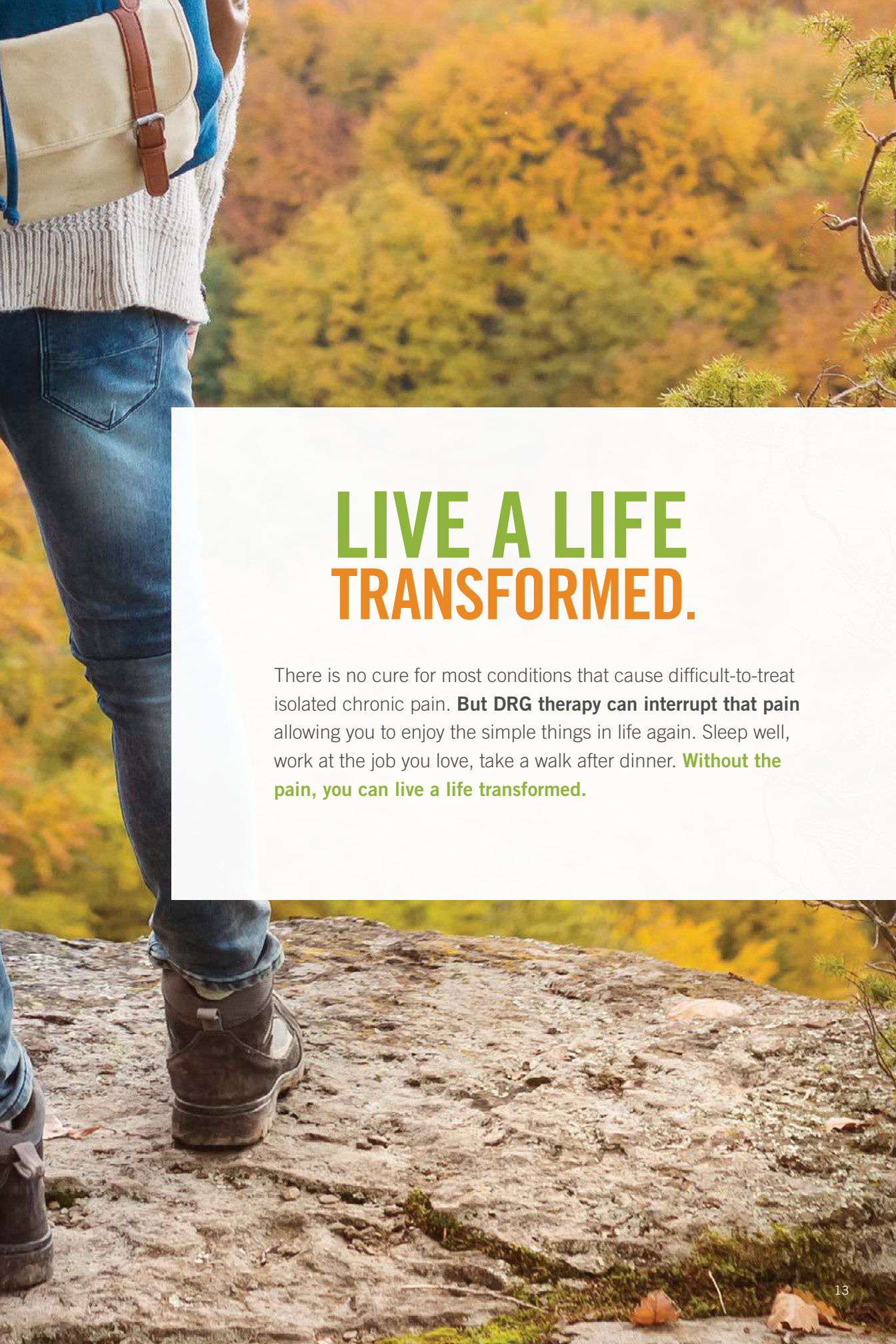


*Compared with the Control group.

94.5% of DRG patients did not experience stimulation **outside** of their primary area of pain at 12 months.*



DRG patients had an average of **81.4%** **REDUCTION** in their pain at 12 months.



LIVE A LIFE TRANSFORMED.

There is no cure for most conditions that cause difficult-to-treat isolated chronic pain. **But DRG therapy can interrupt that pain** allowing you to enjoy the simple things in life again. Sleep well, work at the job you love, take a walk after dinner. **Without the pain, you can live a life transformed.**

CONTACT YOUR DOCTOR FOR MORE INFORMATION.

To learn more about DRG therapy, please speak with your physician and visit **www.sjm.com/pain**

1. Breivik, H., Hattori, S., & Moulin, D.E. (2005). *Prevalence and impact of chronic pain: A systematic review of epidemiological studies on chronic pain.* Presented at the International Association for the Study of Pain (IASP) 11th World Congress on Pain, Sydney, Australia.
2. American Chronic Pain Association. APCA Consumer Guide to Pain Medication and Treatment. http://www.theacpa.org/uploads/ACPA_Resource_Guide_2012_Update%20031912.pdf. Accessed March 11, 2014.
3. Levy, R. & Deer, T. (2015). A prospective, randomized, multi-center controlled clinical trial to assess the safety and efficacy of the Spinal Modulation Axium™ Neurostimulator System in the treatment of chronic pain. Presented at NANS 2015.
4. The American Association of Neurological Surgeons. Spinal Cord Stimulation. http://www.aans.org/Patient Information/Conditions and Treatments/Spinal Cord Stimulation.aspx. Accessed March 21, 2016

Indications for Use: The Axium™ Neurostimulator System is indicated for 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.*

Contraindications: Patients contraindicated for the Axium Neurostimulator System are those who are unable to operate the system and are poor surgical risks. Patients who failed to receive effective pain relief during trial stimulation are contraindicated to proceed to the INS procedure.

Potential Adverse Events: The implantation of a neurostimulation system involves risk. Implant Manual must be reviewed for detailed disclosure.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

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

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

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