DRG THERAPY FOR CHRONIC PAIN

ACCURATE CLINICAL STUDY

FACT SHEET FOR PATIENTS

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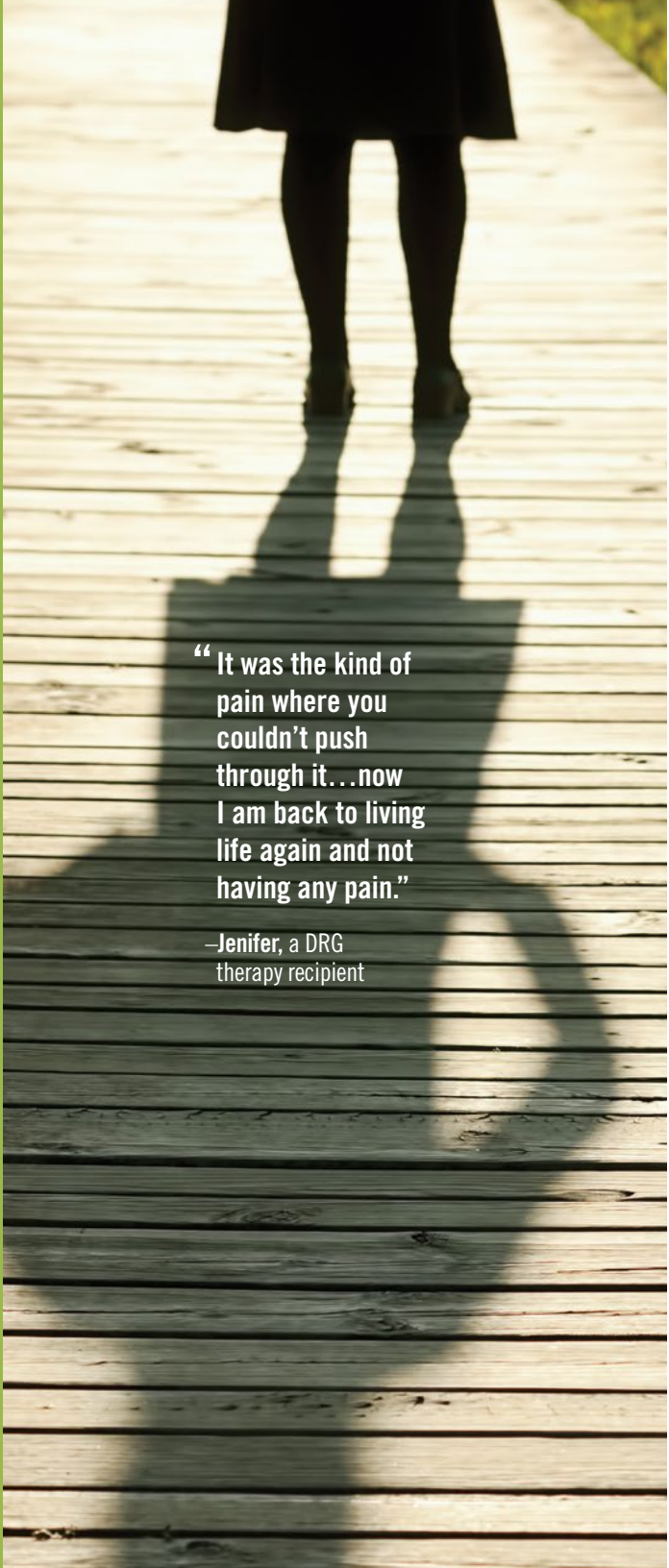
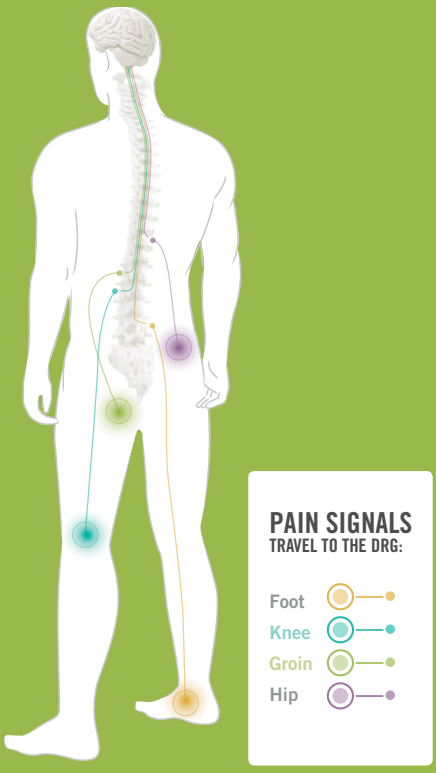


“It was the kind of pain where you couldn’t push through it…now I am back to living life again and not having any pain.”

–**Jenifer,** a DRG therapy recipient

WHAT IS DRG THERAPY?

DRG therapy works much like traditional neurostimulation. Neurostimulation is a therapy that influences the signals sent to the brain through the use of an implanted stimulation device. The therapy uses mild electrical signals to intercept pain signals before they reach the brain. What's different about DRG therapy, as demonstrated in the ACCURATE clinical study, is that it uses electrical pulses to stimulate a cluster of nerve cells in the spinal column called the dorsal root ganglion(s) that directly corresponds to the area of the body where the pain occurs.



WHAT IS THE ACCURATE STUDY?

The ACCURATE clinical study is the largest randomized, controlled neurostimulation trial conducted in patients with complex regional pain syndrome (CRPS) and peripheral causalgia, to assess the safety and efficacy of dorsal root ganglion or DRG stimulation in the treatment of chronic, intractable pain (defined as difficult-to-treat pain that has been present for a minimum of six months[1]).

152 patients enrolled in study

There were 152 subjects with chronic, intractable pain of the lower limbs enrolled and randomized in the ACCURATE clinical study. They were randomized to a DRG stimulation group or a control group (using a traditional neurostimulation device) across 22 investigational sites.

The ACCURATE clinical study was designed to measure whether a new type of neurostimulation, called DRG therapy, can help more patients with difficult-to-treat isolated pain caused by CRPS of the lower limbs. This kind of pain may be focused in a lower extremity (foot, knee, hip or groin); it is believed to be a problem in the nervous system affecting the way pain signals are sent between the brain and the rest of the body. But for patients with CRPS, traditional pain management methods—including traditional neurostimulation—often don't work.

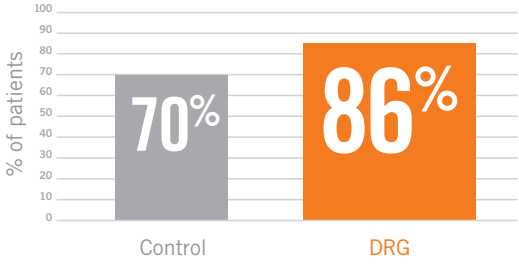
All 152 patients enrolled and randomized in the ACCURATE clinical study experienced chronic pain in a lower extremity.
The pain typically began after an injury, surgery, or other medical intervention and continued for six or more months. Some patients also had one or more other symptoms, including extreme sensitivity to touch or joint movement, changes in skin temperature and/or color, swelling, changes in sweating, decreased range of motion or weakness in motor control. These symptoms are often associated with CRPS, which has previously been known as reflex sympathetic dystrophy (RSD).

WHAT WAS THE GOAL OF THE ACCURATE CLINICAL STUDY?

The goal of the ACCURATE clinical study was to demonstrate safety and efficacy of DRG stimulation as compared to traditional neurostimulation.

WHAT WERE THE RESULTS OF THE ACCURATE STUDY?[2]

86% of DRG patients had persistent pain relief at 12 months*



*Based on Implant Only (IO) population.

DRG patients had an average of

81.4%
REDUCTION
in their pain
at 12 months[2]

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

DRG therapy 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.

If you are interested in learning more about DRG therapy and pain management, please talk to your doctor.

DISCOVER MORE and find a DRG specialist near you at SJM.com/Pain

1. 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.

2. ACCURATE Trial Clinical Report for Protocol 03-SMI-2012 dated January 19, 2016.

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.

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 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.*

CE Mark: The Spinal Modulation™ Neurostimulator System is indicated for the management of chronic intractable pain. **Australia:** The Spinal Modulation implantable neurostimulation system is indicated for spinal cord stimulation (SCS) for the management of chronic, intractable pain of the trunk and/or limbs.

Contraindications:

US: Patients who are unable to operate the system, who are poor surgical risks, or who have failed to receive effective pain relief during trial stimulation.

CE MARK and Australia: Patients who have an active implantable medical device including but not limited to cardiac pacemakers and cardiac defibrillators, are unable to operate the system, and are poor surgical risks.

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 or flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery and equipment, pediatric use, pregnancy, and case damage.

Adverse Effects: Painful stimulation, loss of pain relief, surgical risks (e.g., paralysis). Implant Manual must be reviewed for detailed disclosure. Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events. Implant Manual must be reviewed for detailed disclosure.

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

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