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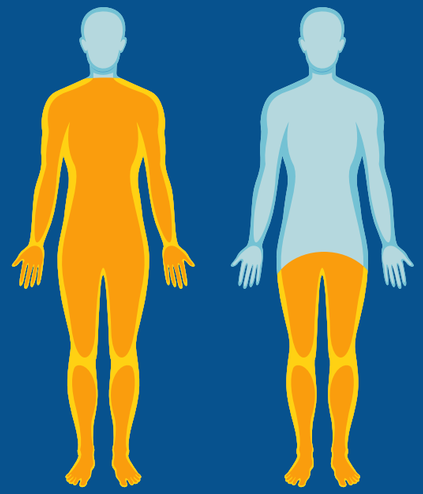

SCS Therapy Indication

Chronic intractable pain of the trunk and/or limb, including pain associated with CRPS.

DRG Indication

Chronic pain of the lower limbs in adult patients with CRPS I and II.

Medtronic
Further, Together

References

1. Deer TR, Levy RM, Kramer J, et al. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. *Pain*. 2017 Apr;158(4):669-681.
2. Schultz. Sensor-Driven Position-Adaptive Spinal Cord Stimulation for Chronic Pain. *Pain Physician* 2012; 15:1-12, ISSN 1533-3159. Page 8.
3. Desai MJ, Hargens LM, Breitenfeldt MD, et al. The rate of magnetic resonance imaging in patients with spinal cord stimulation. *Spine*. 2015;40(9):E531-E537.

Neurostimulation Systems for Pain Therapy:

Brief Summary: Product manuals must be reviewed prior to use for detailed disclosure.

Indications: Implantable neurostimulation systems - A Medtronic implantable neurostimulation system is indicated for spinal cord stimulation (SCS) system 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 conditions:
• Failed Back Syndrome (FBS) or low back syndrome or failed back
• Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or herniated disk
• Postlaminectomy pain
• Multiple back operations
• Unsuccessful disk surgery
• Degenerative Disk Disease (DDD)/herniated disk pain refractory to conservative and surgical interventions
• Peripheral causalgia
• Epidural fibrosis
• Arachnoiditis or lumbar adhesive arachnoiditis
• Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dystrophy (RSD), or causalgia

Contraindications: Diathermy - Do not use shortwave diathermy, microwave or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the locations of the implanted electrodes, resulting in severe injury or death.

Warnings: Sources of strong electromagnetic interference (e.g., defibrillation, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the neurostimulation system, resulting in serious patient injury or death. These and other sources of EMI can also result in system damage, operational changes to the neurostimulator or unexpected changes in stimulation. Rupture or piercing of the neurostimulator can result in severe burns. An implanted cardiac device (e.g., pacemaker, defibrillator) may damage a neurostimulator, and the electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device.

Precautions: The safety and effectiveness of this therapy has not been established for pediatric use (patients under the age of 18), pregnancy, unborn fetus, or delivery. To properly assess test stimulation, patients should be detoxified from narcotics prior to lead placement. Clinicians and patients should follow programming guidelines and precautions provided in product manuals. Patients should avoid activities that may put undue stress on the implanted neurostimulation system components. Patients should not scuba dive below 10 meters of water or enter hyperbaric chambers above 2.0 atmosphere absolute (ATA). Electromagnetic interference, postural changes, and other activities may cause shocking or jolting. Patients using a rechargeable neurostimulator should check for skin irritation or redness near the neurostimulator during or after recharging.

Adverse Events: Adverse events may include: undesirable change in stimulation described by some patients as uncomfortable, jolting or shocking; hematoma, epidural hemorrhage, paralysis, seroma, CSF leakage, infection, erosion, allergic response, hardware malfunction or migration, pain at implant site, loss of pain relief, chest wall stimulation, gastrointestinal symptoms (diarrhea, constipation, and leakage of stool), bladder symptoms (urinary retention and frequency and leakage of urine) and surgical risks.

For further information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com.

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ACCURATE.
WHAT DOES THE EVIDENCE TELL US?

Learn about the INCREASED risks *associated with Abbott's DRG Stimulation*

Medtronic
Further, Together

ACCUR
UNVEIL

Dorsal Root Ganglion (DRG) Stimulation Therapy

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 pain of the lower limbs in adult patients with CRPS I and CRPS II.

CONSIDER ALL OF THE RISKS WITH DRG STIMULATION

**Clinical data extracted from Abbott's ACCURATE Study*

1

SCS VS. DRG: VAS SCORE COMPARISON

Average VAS score reductions at 12 months:
From 80.6 to 15 mm with DRG and 80.7 to 26.5 mm with SCS[1]

Resulting in an 11.5 mm difference in average pain scores

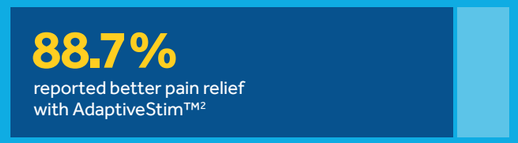
*SCS demonstrated **clinically significant relief** in patients' pain*

2

SUBOPTIMAL USE OF SCS IN THE STUDY

AdaptiveStim™ was turned off for the length of the ACCURATE study.

Results from the RestoreSensor™ study demonstrated better pain relief with AdaptiveStim™ vs. conventional stimulation.[2]



*Is the ACCURATE study **a fair comparison?***

3

PROCEDURE TIME

Average implant procedure time for DRG was

42%
longer than SCS[1]

DRG: 107.2 min average (+/-51.2 minutes)
SCS: 75.7 min average (+/- 32.2 minutes)

*What does **prolonged** procedure time mean to you?*

4

INCREASED PROCEDURE-RELATED RISKS WITH DRG

Patients with DRG had almost

2x *the amount of procedure-related complications[1]*
vs. patients with SCS

DRG Stimulation: 46% complication rate
SCS Therapy: 26% complication rate

** There was no difference in serious and device-related AE rates.*

Consider ALL the risks with DRG.
What's best for your patient?

SCS achieved clinically significant pain relief for patients *with* fewer procedure-related complications.

! Restricted access to MRI with DRG

Approximately 82% of spinal cord stimulator (SCS)-implanted patients are expected to need at least one MRI within 5 years of implant[3]