



INTERVENTIONAL PAIN MANAGEMENT

Dorsal Root Ganglion Stimulation

WHAT IS CHRONIC PAIN?

Chronic pain is a largely under-treated and misunderstood disease that affects millions of people worldwide. It is defined as moderate to severe pain that persists for one or more months longer than would generally be expected for recovery to a specific disease, injury or surgery. According to the National Institutes of Health, 90 million people in the U.S. suffer from chronic pain. The American Pain Foundation estimates that chronic pain costs approximately \$100 billion per year in lost work time and health care expenses.

In their search for relief, patients often endure inadequate treatments and struggle with prescription painkillers. In a report issued by the U.S. Department of Health & Human Services, the number of narcotics, analgesic, drug abuse-related emergency room visits increased 20 percent over the course of one year, totaling 108,320 visits in 2002. The 45-54 age groups experienced the largest increase (298 percent).



WHAT IS CRPS?

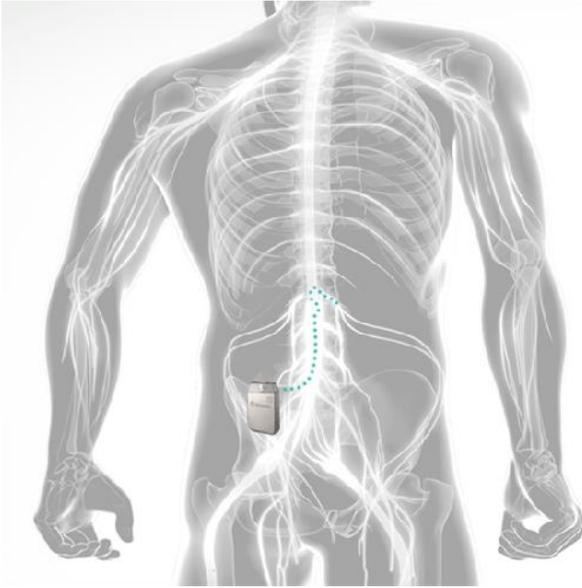


Complex Regional Pain Syndrome (CRPS) is a chronic pain condition that affects a part of the body following an injury or trauma. CRPS is felt to be caused in part by damaged or malfunctioning nerves. CRPS affects the way the central nervous system and the peripheral nervous system send pain signals from the brain and spinal cord to the rest of the body. Often characterized by prolonged or excessive pain, CRPS can cause mild or dramatic changes in skin color, temperature, and/or swelling in the affected area. Patients with confirmed nerve injuries are categorized as having CRPS-11 (also known as causalgia), while patients without confirmed nerve injury are classified as having CRPS-I (previously called reflex sympathetic dystrophy syndrome or RSDS).

WHAT ARE SPINAL CORD STIMULATORS?

Spinal cord stimulators are implanted devices that are similar in function and appearance to cardiac pacemakers, except that the electrical pulses are sent to the spinal cord instead of the heart. These "pacemakers for pain" interrupt the pain signals' pathways to the brain by delivering low intensity electrical pulses to trigger selective nerve fibers along the spinal cord. Researchers theorize that stimulating these nerve fibers diminishes or blocks the intensity of the pain message being transmitted to the brain, replacing feelings of pain with a more pleasant tingling sensation called paresthesia.





WHAT IS THE ST. JUDE MEDICAL AXIUM™ NEUROSTIMULATOR SYSTEM?

The Axiu™ Neurostimulator System is the first and only neurostimulation device designed for dorsal root ganglion (DRG) stimulation. By stimulating the DRG, a spinal structure densely populated with sensory nerves that transmit information to the brain via the spinal cord, the St. Jude Medical Axiu system delivers a form of spinal stimulation that gives physicians the ability to treat the specific areas of the body where pain occurs. For patients with neuropathic chronic intractable pain associated with CRPS -conditions underserved by traditional SCS -stimulation of the DRG can provide pain relief when previous treatment options have not provided adequate pain relief.

DATA FROM THE ACCURATE STUDY TO SUPPORT DRG STIMULATION

Results from the ACCURATE IDE study, the largest study to date evaluating patients suffering from neuropathic chronic intractable pain associated with CRPS or peripheral causalgia, showed a statistically significant number of patients receiving DRG stimulation achieved meaningful pain relief and greater treatment success when compared to patients receiving traditional SCS. Patients in the study were randomized to receive DRG stimulation delivered by the Axiu Neurostimulator System or conventional tonic SCS therapy, and nearly all the patients receiving DRG stimulation reported better stimulation targeting in their area of pain without extraneous paresthesia than patients receiving traditional SCS. After 12 months, more than a third of patients who received DRG stimulation were experiencing greater than 80 percent pain relief with no paresthesia.

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