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FDA approves Boston Scientific's spectra wavewriter spinal cord stimulator system

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The system allows physicians and patients to combine therapeutic options, customize therapy and capture real-time feedback designed to treat chronic and debilitating pain successfully.

Singapore - Boston Scientific Corporation announced that the U.S. Food and Drug Administration (FDA) has approved the Spectra WaveWriter Spinal Cord Stimulator (SCS) System. It is the first and only system approved by the FDA to simultaneously provide paresthesia-based and sub-perception therapy. The system allows physicians and patients to combine therapeutic options, customize therapy and capture real-time feedback designed to treat chronic and debilitating pain successfully.

SCS works by sending low electrical pulses, which vary in frequency, pulse width and amplitude, to the spinal cord to interrupt pain signals. Paresthesia-based therapy provides pain relief with a light tingling sensation while sub-perception therapy works without that sensation. With the Spectra WaveWriter System, patients can choose to combine both of these therapies to target one specific area of pain or use each therapy as needed to best manage multiple areas of pain. Patients provide real-time feedback using the system's remote control. Together, these features benefit patients by addressing each individual's unique pain relief needs.

"Patients suffering with chronic pain experience pain differently, and pain also evolves over time, sometimes causing a patient to become less responsive as the body becomes accustomed to treatment," said Dr. Giancarlo Barolat, neurosurgeon, Barolat Neuroscience, Denver, Colorado. "Until now, the medical community has had limited options to offer personalized pain relief therapy to patients. The main advantage of the Spectra WaveWriter System is that it integrates multiple therapies into a single device so that treatment can more easily be tailored to individual needs."

The Spectra WaveWriter System was developed with more than a decade of clinical research focused on optimizing sub-perception and delivering multiple therapies intended for more effective, long-term pain relief. These studies include the WHISPER study and the PROCO study. The PROCO study was a multi-center, prospective, double-blind, randomized study in which patients acted as their own control. This study established in de novo patients that similar pain relief and improvement in quality of life measures are achieved independent of the type of frequency (from 1 kHz up to 10 kHz) used in sub-perception SCS therapy when the proper target and dose are identified. The WHISPER study is a multi-center, prospective, cross-over, randomized, and controlled study evaluating the long-term safety and effectiveness of sub-perception SCS pain relief therapy.