



HF10™ Therapy Fact Sheet

Traditional SCS Therapy vs. HF10™ Therapy

Spinal cord stimulation (SCS) is an established pain treatment that delivers electrical pulses to the spinal cord to alter the transmission of abnormal pain signals to the brain. The electrical pulses are delivered by small electrodes that are placed in the spinal epidural space and connected to a compact battery-powered generator implanted under the skin.

Traditional SCS therapy typically delivers electrical pulses at a frequency below 1,200 Hz, and more commonly between 40-60 Hz. Traditional SCS therapy attempts to “mask” a patient’s sensation of pain by covering the area of pain with paresthesias. Paresthesias are stimulation-induced sensations, commonly perceived as tingling, prickling, pins-and-needles, or vibrating sensations. HF10 therapy is different from traditional SCS therapy in that it relieves pain without paresthesia. Specifically, HF10 therapy uses a 10,000 Hz frequency and additional proprietary factors including waveform characteristics, lead placement and programming to provide a therapy that has been confirmed by the FDA to be superior to traditional SCS therapy.

Traditional SCS Therapy	HF10 Therapy
Frequency: Typically operates below 1,200 Hz and generally at 40-60 Hz	Frequency: Operates at 10,000 Hz
Paresthesia-Based: Goal is to “mask” pain with a stimulation-induced sensation called paresthesia	Paresthesia-Free: Goal is to offer substantial pain relief without any paresthesia

FDA Approval of HF10 Therapy

Since 2010, HF10 therapy (Nevro’s proprietary SCS therapy) has been used commercially in over 3,000 patients in Europe and Australia, thus demonstrating it as a safe and highly effective therapy for patients living with chronic back and leg pain.

In May 2015, Nevro’s Senza® SCS system, which is the only SCS system that delivers HF10 therapy, was approved by the FDA. The FDA approval for HF10 therapy came with a label of superiority over traditional SCS therapy, indicating that HF10 therapy was found to be statistically superior to traditional SCS therapy in terms of response rate and magnitude of pain relief for patients with back and leg pain. HF10 therapy is the only SCS therapy approved by FDA with a superiority labeling.

Additionally, the FDA indicated HF10 therapy to be a paresthesia-free therapy, also a novel and unique distinction in the SCS space. As such, HF10 therapy is the only SCS therapy approved by FDA to be paresthesia-free, and the only SCS therapy that can be used without patient restrictions on motor vehicle operation while receiving therapy.

The basis for the approval and the superiority labeling was the SENZA-RCT pivotal trial¹, a ground-breaking clinical study that was the first to directly compare two competing SCS therapies. In the SENZA-RCT, HF10 therapy demonstrated meaningfully superior results to traditional SCS therapy for back and leg pain, including superior response rates, pain relief, and functional outcomes. Superiority was demonstrated in the primary and all secondary endpoints including at every measurement time point



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throughout 12 months of follow-up¹. In the SENZA-RCT, patients receiving HF10 therapy had a 1.5x greater likelihood of responding to the therapy over traditional SCS therapy. In addition, HF10 therapy patients achieved approximately a 50% greater improvement in pain score than those with traditional SCS therapy.

SENZA-RCT follow-up and reporting will continue through 24 months of therapy delivery.

In summary, the innovative nature of Nevro's Senza SCS system and HF10 therapy is demonstrated on several fronts:

- HF10 therapy is the only SCS therapy approved by FDA with superiority labeling
- HF10 therapy is the only SCS therapy indicated by FDA to provide pain relief without paresthesia
- HF10 therapy is the only SCS therapy approved by FDA to be used without patient restrictions on motor vehicle operation while receiving therapy
- The Senza system is the only implantable SCS system approved by FDA with labeling for 3T conditional MRI compatibility for head and extremities scans.

CLINICAL DATA SUMMARY

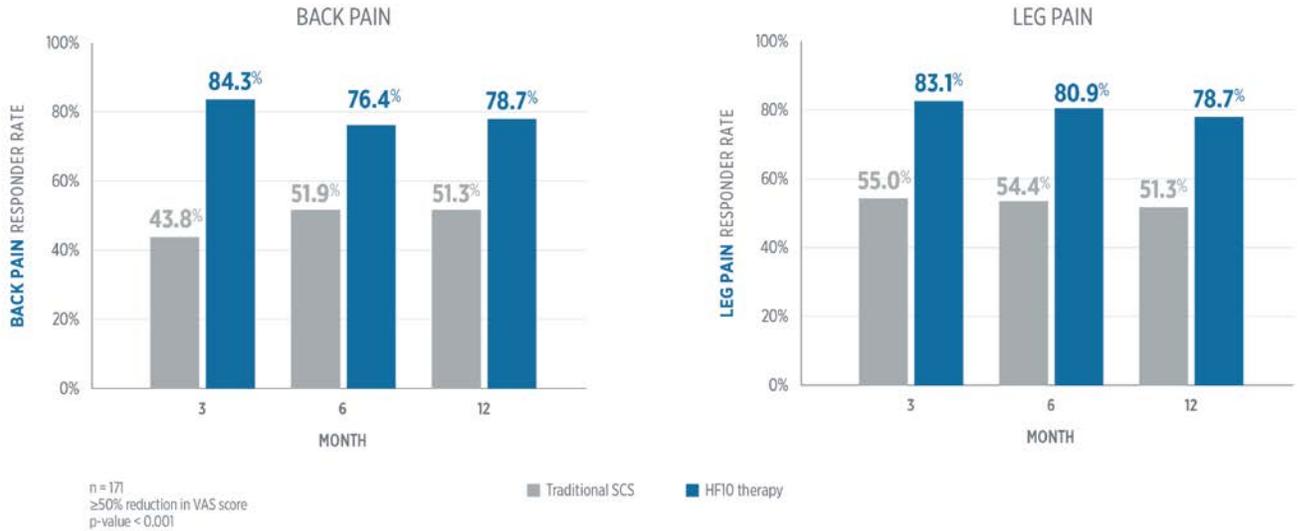
The SENZA-RCT compared HF10 therapy to commercially-approved traditional SCS therapy. HF10 therapy was demonstrated to be superior to traditional SCS therapy at all primary and secondary endpoints, resulting in greater pain relief in a greater number of patients. Additionally, HF10 therapy cases required no paresthesia mapping and HF10 therapy patients experienced no paresthesias, resulting in a paresthesia-free indication from the FDA. Finally, HF10 therapy was shown to have an equivalent safety profile to traditional SCS therapy.



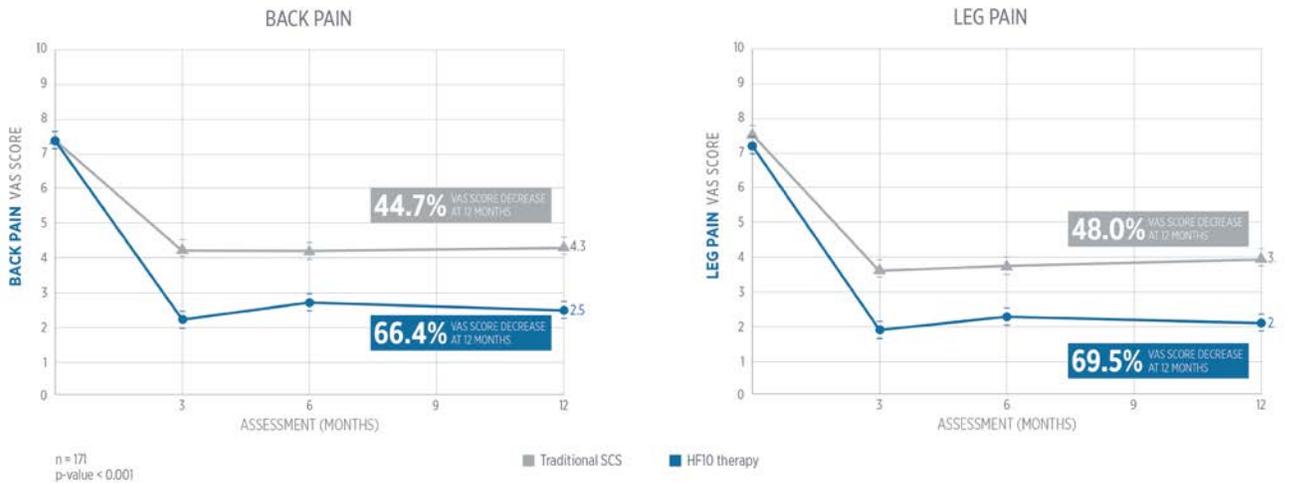
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HF10 Therapy Efficacy

SUPERIOR RESPONSE RATES WITH HF10 THERAPY¹



SUPERIOR PAIN RELIEF WITH HF10 THERAPY¹



1. Kapural L, et al. Comparison of 10 kHz high-frequency SCS to traditional low-frequency SCS: the SENZA-RCT U.S. pivotal study. Presented at: 18th Annual North American Neuromodulation Society Conference; December 11-14, 2014; Las Vegas, NV.



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Paresthesia Free: No Uncomfortable Stimulation

In the SENZA-RCT, patients with HF10 therapy did not report feeling any paresthesias, and therefore did not report any uncomfortable stimulation. Patients receiving paresthesia-based traditional SCS therapy reported the paresthesias as being “uncomfortable” nearly half the time the therapy was being applied.

SENZA-RCT: PATIENTS REPORTING UNCOMFORTABLE STIMULATION¹

	HF10 THERAPY n = 90	CONTROL (TRADITIONAL) n = 81
MONTH 3	0 (0%)	33 (46.5%)
MONTH 12	0 (0%)	28 (44.4%)

¹ Kapural L, et al. Comparison of 10 kHz high-frequency SCS to traditional low-frequency SCS: the SENZA-RCT U.S. pivotal study. Presented at: 18th Annual North American Neuromodulation Society Conference; December 11-14, 2014; Las Vegas, NV.

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