

## Fast Facts: Diabetes Related Neuropathy Pain and HFX™ 10 kHz Spinal Cord Stimulation (SCS) System

## Painful Diabetic Neuropathy (PDN): A Chronic, Debilitating Pain with Limited Treatment Options

- 34 million people have diabetes in the U.S.¹ and roughly half of all adults with diabetes will suffer from diabetic neuropathy in their lifetime²
- ~2.3MM patients suffer from PDN with no relief from current treatments<sup>3</sup>
- Diabetic neuropathy is caused by chronically high blood sugars
- Nerve damage can cause pain and numbness that can make you more vulnerable to falls, burns, infections, ulcers and longer-term complications.
- Painful diabetic neuropathy can significantly interfere with a person's quality of life, sleep and functionality.

## **Current Treatments Leave Room for Improvement**

- Treatment options include over-the-counter medications, prescription medications, physical therapy or injections, however for many patients these options are inadequate for long-term relief.
- Opioids, a commonly used tool in the management of diabetes related neuropathy, also present addiction potential, long-term dependence and show little evidence of improved function.
- New federal guidelines aimed at reducing opioid misuse and abuse has resulted in some physicians denying
  or limiting opioid therapy for some chronic pain sufferers. Physicians need better clinical and interventional
  tools to treat complex chronic pain.
- Roughly 45% of PDN patients are refractory to the traditional treatment options
- Finally, HFX provides a non-drug treatment for diabetes related neuropathy pain.

## A Safe and Effective Treatment for Painful Diabetic Neuropathy: HFX for PDN

- A new treatment is available to help you manage shooting, burning, pins and needles pain associated with diabetic neuropathy
- Introducing HFX™ for PDN, a Senza spinal cord stimulation system that uses 10 kHz Therapy to treat pain from diabetic neuropathy.
- The HFX™ Solution for Painful Diabetic Neuropathy (PDN) provides significant pain relief without the side effects of conventional medical management
- HFX for PDN is the only spinal cord stimulator (SCS) system FDA approved with a specific indication for painful diabetic neuropathy.
- HFX 10 kHz Therapy calms the nerves and interrupts the transmission of pain signals to the brain, alleviating pain and improving quality of life.
- HFX 10 kHz Therapy is the most studied SCS therapy available and has been used to treat more than 70,000 patients with chronic pain.
- The effectiveness of HFX 10 kHz Therapy in controlling pain associated with diabetes related neuropathy compared to conventional treatments was tested in a large clinical study.<sup>4</sup>
- 85% of patients achieved at least 50% pain relief<sup>4</sup>
- An average 76% decrease in lower limb pain<sup>4</sup>
- 92% of patients were satisfied with their treatment<sup>4</sup>
- Significantly reduces pain and improves sleep<sup>4</sup>
- Reduces painful sensations like burning, tingling, and numbness<sup>4</sup>
- Patients can evaluate HFX for PDN in a temporary trial before having the device implanted. The implant
  procedure requires a minimally invasive outpatient procedure.
- HFX provides physicians and patients with a comprehensive solution to treat the complex and dynamic nature
  of chronic pain. As the nature of pain can change over time, vary in intensity or occur in different parts of the
  body, HFX provides the most flexible platform that allows patients to have access to all SCS frequencies and
  the most waveforms over the long term. Physicians no longer have to choose between traditional SCS
  therapy or 10 kHz Therapy. With HFX, they get both.



- CDC National Diabetes Statistics Report 2020; Schmader KE. Epidemiology and impact on quality of life of postherpetic neuralgia and painful diabetic neuropathy. Clin J Pain. 2002;18(6):350-354; Trinity Partners Market Research 2017 Petersen, E, et. al. Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy A Randomized Clinical Trial. JAMA Neurology, April 2021.