

dance

take a trip

garden

ride a bike

play catch

hit the gym

walk the dog

shop

go out on the town

host a dinner party

hike

walk on the beach

Liberate yourself from chronic pain

Free to

HFX[™]
Relief, multiplied.[™]

INTRODUCTION TO HFX[™]
SPINAL CORD STIMULATION

What is HFX?

An innovative chronic pain treatment.

HFX is a comprehensive solution that includes a Senza spinal cord stimulation system and support services for the treatment of chronic pain.

HFX includes the widest range of SCS frequencies and waveforms available: 2-1,200 Hz & 10,000 Hz.

Causes of chronic pain

Damaged nerves can overproduce pain signals. The stronger the signal, the stronger the pain.

Chronic pain is a persistent, debilitating pain that lasts for three months or longer.

It is different from acute pain, which commonly results from injury or surgery and heals with time.

Chronic pain affects roughly 1.5 billion people worldwide and is most commonly located in the back.

Chronic pain generally falls into one of two categories. There is mechanical pain, which is generally caused by damage to the bones or muscles. There is also nerve pain, where it is more difficult to identify the source. It may come from an illness, accident, or injury to the nerves - or appear for no reason at all. That's why it's so difficult to manage. Many patients have a mix of both pain types.

Doctors may prescribe medications, surgery, or injections. The goal is to find a treatment tailored to fit individual needs. However, individual responses to these treatments vary, and may leave patients unsatisfied or managing unwanted side effects.

Limitations of common treatments for chronic pain.

Prescription medications

Shown to be effective for acute pain, however limited effectiveness for chronic pain. There are also significant risks of addiction and side effects, such as constipation.

Spinal surgery

Appropriate for correcting mechanical issues, but often ineffective for resolving debilitating nerve pain. It's the most invasive option.

Epidural steroid injections

Often effective for short-term pain relief, but usually ineffective for sustained pain relief. Also requires frequent office visits.

Introducing Spinal Cord Stimulation (SCS) for chronic pain relief

Evidence shows that delivering mild electrical pulses to the nerves interrupts the transmission of pain signals to the brain, thus reducing pain.

- SCS is a well-established approach to managing chronic pain used globally for over 30 years.
- It includes a small implanted device that transmits mild electrical pulses to the spinal cord.
- The pulses calm the nerves and reduce pain signals to the brain.

HFX includes 10 kHz Therapy, which has shown superior results for back and leg pain vs. traditional SCS.

HFX is proven to deliver meaningful long-term pain relief

HFX is the most advanced SCS available, offering a wide range of benefits.

HFX may assist in the management of persistent back and leg pain.

88% of HFX patients are more independent because of their reduced pain.²

HFX offers the widest range of frequencies and waveforms available to individualise your relief.

With HFX, relief starts shortly after the procedure and 4 out of 5 people experience significant pain relief.¹

HFX calms the nerves and interrupts the transmission of pain signals to the brain.

- HFX is not a medication-based treatment, but does require surgery. Any surgery carries risks.
- HFX interrupts the transmissions of chronic pain signals, but still allows you to feel everything else as you should.
- HFX is proven to provide long-term pain relief.⁴
- Talk to your healthcare professional about whether this product may be suitable for you as part of your overall plan to manage chronic pain. This product may not be suitable for you.

Note: HFX does not require prescription pain medications to provide pain relief. Your physician may temporarily prescribe medications during or after your HFX procedure. HFX clinical claims are supported by results with 10 kHz Therapy, one of several options available with HFX.

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You can try HFX, before you decide

In just a week, you can discover if HFX is right for you.

The trial system delivers the same therapy as the implant. If you and your doctor agree that HFX works for you, you can go forward with the implant to use HFX continuously.

The trial begins with a simple procedure that can be performed in your doctor's office or a local outpatient facility.

The HFX trial device is worn under your clothes.

The system is customised for your pain, and then you evaluate your pain relief and improvement to your daily activities.

9 out of 10 people who try HFX choose to keep it.¹

The HFX implant procedure

A successful trial opens the door to continuing with HFX.

During a quick and minimally invasive procedure, a small device is implanted under the skin, just above the beltline or in the buttocks area. It's connected to thin, flexible wires just like those used in the trial, that are placed near the spine.

Implanting the device is typically an outpatient procedure, which means you will likely go home the same day.

It's also possible your doctor may recommend a different type of approach affiliated with a "paddle lead," which requires a slightly different procedure.



Note: Trial durations vary and will be determined by your treating physician.

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Frequently asked questions

I've tried everything. Why should I try this?

HFX may aid in the management of persistent back and leg pain. It has also proven successful for people who have had surgery or tried other pain therapies.

Is it safe?

Yes. HFX safely delivers stimulation that doesn't interfere with normal sensory perception, cognitive abilities, or motor functions. It doesn't interact with medications you are currently taking. It does not require surgery and there are risks associated with all surgical procedures. However, the implant is completely reversible.

How long will the trial period last?

The trial is typically 5 to 7 days, depending on the need for adjustments to tailor HFX to you.

Will I feel anything?

Unlike many SCS systems, HFX offers programs that do not create a tingling sensation, known as paresthesia.

How will my doctor know if it's working?

You will be involved every step of the way, giving your doctor feedback and making sure HFX is programmed to meet your needs.

How do I access HFX?

HFX is covered under private health insurance. The level and waiting periods may vary depending on the provider, we recommend you confirm the coverage level directly with your insurer.

Will it interfere with sleep?

Unlike many SCS systems, HFX offers programs that can remain on while you sleep.

Can I drive?

Unlike many SCS systems, HFX offers programs that can be used while driving.

Do I need to change my medication?

HFX may reduce or eliminate the need for pain medications, however always discuss medications with your healthcare professional before making adjustments.

Can I turn it off if I need to?

Yes. The system includes a remote control device that lets you turn HFX off and on.

Can I have an MRI with HFX?

Yes. HFX is conditionally approved for MRI scans.

How do I know if HFX is right for me?

The best way to know if HFX is right for you is to ask your healthcare professional. It may be helpful to know HFX is for people experiencing chronic pain after trying surgery, physical therapy or pain medications. Depending on your medical condition, HFX may not be right for you.

Ask your healthcare professional for a HFX trial.

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Rx Only: Patient experiences with the Senza[®], Senza II[™] and Senza Omnia[™] neuromodulation systems vary by individual, including the amount of pain relief. The occurrence of adverse effects associated with SCS implant surgery or use also varies by patient.

Brief Summary: A summary of important information follows. Please see www.NevroHFX.com/safety and the Senza[®], Senza II[™] and Senza Omnia[™] Patient Manual (at <https://www.nevro.com/manuals>) for complete information. Please consult your doctor to fully understand Senza[®], Senza II[™] and Senza Omnia[™] benefits and risks.

Indications for Use: Senza[®] Omnia[™]: The Senza[®] Omnia[™] IPG kit is a component of the Senza[®] Omnia neuromodulation system, which is indicated 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: failed back surgery syndrome, intractable low back pain, and leg pain. Senza[®]: The IPG Kit consists of an implantable pulse generator which is a component of the Nevro Spinal Cord Stimulation System that is intended to aid in the management of chronic intractable pain of the trunk and/or limbs.

References: 1. Kapural L., et al. Novel 10-kHz High-frequency Therapy Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain. *Anesthesiology*, 123(4) 2. Calculated from patient survey data and functionality measures within the SENZA-RCT. Data on file. 3. Al-Kaisy A, Van Buyten J-P, Smet I, Palmisani S, Pang D, Smith T. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. *Pain Med.* 2014;15:347-354 4. Kapural L, et al. Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-month Results from a Multicenter, Randomized, Controlled Pivotal Trial. *Neurosurgery*. Published 09 2016 [Epub ahead of Print]