

## Frequently Asked Questions

### ① What treatment will I receive as part of this study?

There will be two treatment groups, and you have a 50-50 chance of being assigned to either. In the first group, you will continue with standard treatments for your condition. In the second group, you will try Nevro HFX in addition to your standard treatments.

### ② What if the assigned treatment doesn't give me pain relief?

If your pain relief is insufficient and you're unhappy with your treatment after 6 months, you may qualify to switch over to the other treatment group.

### ③ How does the Nevro HFX procedure work?

There is a temporary trial procedure, or a "test drive," which usually lasts 5-7 days. If this successfully reduces your pain, you and your doctor will discuss a more permanent implant.

### ④ Will I feel anything with Nevro HFX?

No, you shouldn't feel anything. Unlike other similar devices, Nevro HFX doesn't create a tingling or buzzing sensation, known as paresthesia, letting you just feel relief.

### ⑤ Can I turn Nevro HFX off if I need to?

Yes, you will have control over your therapy and can turn it off using your remote control.

### ⑥ Can I travel with Nevro HFX?

Yes, traveling is easy and you can fly with Nevro HFX.

## How do I qualify for this study?

- Have you been diagnosed with painful diabetic neuropathy of the feet and/or legs?
- Do you have partial or full loss of sensation in your feet?
- Have you tried standard treatment approaches?
- Will you be 22 years of age or older at the time of enrollment?
- Are you able to attend study visits at the clinic listed below?

**If you answered yes to these questions, you may be eligible.**

For more information or to find out if this study is suitable for you, please contact the doctor below:

This study is sponsored by Nevro Corp. and conducted by  
Find more information at <https://clinicaltrials.gov/ct2/show/NCTXXXXXXX>

- <sup>1</sup> Petersen EA, Stauss TG, Scowcroft JA, et al. (2021). Effect of High-Frequency (10-kHz) Spinal Cord Stimulation on Patients with Painful Diabetic Neuropathy: A Randomized Clinical Trial. *JAMA Neurology*, 78(6): 687-698.
- <sup>2</sup> Petersen EA, Stauss TG, Scowcroft JA, et al. (2022). High-Frequency 10-kHz Spinal Cord Stimulation Improves Health-Related Quality of Life in Patients with Refractory Painful Diabetic Neuropathy: 12-Month Results from a Randomized Controlled Trial. *Mayo Clinic Proceedings: Innovations, Quality & Outcomes*, 6(4): 347-360.

**Important information:** Rx Only: Patient experiences with the Nevro HFX spinal cord stimulation (SCS) system vary by individual, including the amount of pain relief. The occurrence of adverse events associated with SCS implant surgery or use also varies by patient. Please see [www.NevroHFX.com/safety](http://www.NevroHFX.com/safety) for complete safety, indications for use, and contraindications information.

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# Do you suffer from pain and loss of sensation in your feet or legs due to diabetic neuropathy?

You may be eligible to participate in a clinical trial evaluating Nevro HFX™ for the treatment of your painful diabetic neuropathy



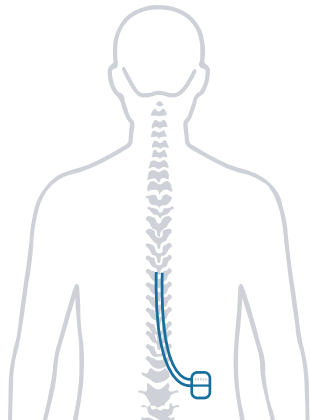
## What is Nevro HFX?

Nevro HFX is a small FDA-approved device that works inside the body to quiet pain signals, potentially providing long-term pain relief and improving quality of life.

### Why your doctor may recommend treatment

If you suffer from pain, you are not alone. Pain is the most common reason for physician visits in the United States. Living with severe pain can significantly interfere with your quality of life. There are many treatment options for chronic pain and your physician may recommend different treatments depending on the type of pain and severity of pain.

Spinal stimulation is a proven therapy that offers a treatment option for painful diabetic neuropathy.



# For over 10 years, Nevro HFX has been proven to safely treat multiple chronic pain conditions in more than 100,000 people.

Through numerous clinical studies, Nevro HFX demonstrated a number of key benefits:



Significant reduction in pain of the legs and feet



Improved quality of life



Reduction of opioid use



Pain relief without paresthesia, a buzzing sensation that may occur with other similar devices

This clinical study is evaluating Nevro HFX as a treatment for pain and loss of sensation in people with diabetic neuropathy.

## What to Expect

If you qualify for and choose to participate in the study, you will be randomly assigned to 1 of the 2 groups under your study physician's care:

### ① Conventional medical treatments:

You may receive a variety of treatments, like medications and physical therapy.

### ② Nevro HFX and conventional medical treatments:

In addition to your standard treatments, you'll try Nevro HFX with a temporary device. If successful, then you may get the implant.

### Trial phase

- The trial requires a minor surgical procedure to place thin leads in the back.
- The leads are then connected to an external device that is taped to your back and easily covered under your clothes.
- During this period, the system's programs are adjusted to best alleviate pain.

If you get at least 50% pain relief during your trial, then you'll have the option to move forward with the implant.

### Permanent phase

If you and your doctor decide to proceed, you will receive another minor, reversible surgical procedure to place the device beneath the skin.