



NEW HOPE

FOR CHRONIC BACK PAIN AND LEG PAIN SUFFERERS

As anyone with chronic back pain and leg pain knows, response to pain therapies can be as individual as the pain experience itself. That's why information about new treatment options is critical. HF10™ therapy is a breakthrough treatment approved by the FDA for chronic back pain and leg pain. If you or someone you love continues to suffer despite trying different treatments, read on to find out what HF10 therapy is and how it's been proven to relieve back pain and leg pain.

FDA-APPROVED AS SUPERIOR TO TRADITIONAL SPINAL CORD STIMULATION

In May 2015, the FDA approved a new treatment for chronic back pain and leg pain called HF10 therapy. While it's technically considered spinal cord stimulation (SCS), HF10 therapy is a game-changer for pain sufferers. It is the only SCS system to ever receive a superiority designation from the FDA for both chronic back pain and leg pain. HF10 therapy is also the only SCS system to deliver significant pain relief without any uncomfortable tingling or buzzing, known as paresthesia.

To put this new therapy to the test, the maker of HF10 therapy carried out the first-ever randomized, controlled clinical trial to compare the relative effectiveness of two SCS systems. The study followed 171 patients using HF10 therapy or traditional SCS for 12 months to measure how many patients responded to treatment and their levels of pain relief.

Results from the clinical study showed that nearly twice as many patients achieved dramatic relief from back pain and leg pain with HF10 therapy as with traditional SCS. The study also demonstrated that eight out of ten patients with severe back pain or leg pain who used HF10 therapy experienced significant pain relief.

The fact that HF10 therapy provided significant relief from back pain, as well as leg pain, is considered an important result because back pain has historically been challenging to treat with spinal cord stimulation.

Even the FDA, in an unusual move, judged the results from the study strong enough to support its superiority when they approved HF10 therapy.

HF10 THERAPY

HF10 THERAPY: THE ONLY FDA-APPROVED PARESTHESIA-FREE THERAPY

HF10 therapy brings another unique advance to SCS because it effectively manages chronic pain without the tingling or buzzing feeling known as paresthesia. HF10 therapy stands for high-frequency stimulation delivered at 10 kilohertz, which is much higher than other approved stimulation technologies.

Traditional, or low-frequency, SCS therapy attempts to mask pain by covering the pain area with stimulation-induced paresthesia. Patients describe the sensation as tingling, prickling, pins-and-needles or vibrating. Many consider it to be an unpleasant side effect of traditional SCS because it feels uncomfortable and is a constant reminder of the pain.

THERE WAS NO PAIN AND NO PARESTHESIA.

“WHEN I USED HF10 THERAPY, I WAS SPEECHLESS BECAUSE I DIDN'T FEEL ANYTHING. I THOUGHT, 'IT'S NOT WORKING. MAYBE THERE'S SOMETHING WRONG'. IT REALLY TOOK ME OFF GUARD. THERE WAS NO PAIN AND THERE WAS NO PARESTHESIA. I FELT NORMAL - LIKE I DID BEFORE I EVER HURT MY BACK. I KNOW THIS SOUNDS A LITTLE DRAMATIC, BUT HF10 THERAPY REALLY HAS CHANGED MY LIFE.”

U.S. STUDY PATIENT

HF10 therapy is the first and only SCS system approved by the FDA that does not rely on paresthesia to provide pain relief. And unlike traditional SCS, HF10 therapy won't give you an unexpected shock when you bend or twist, or engage in other daily activities. As a result, HF10 therapy can stay on while you drive or sleep.

HF10 therapy can be switched on and off with the remote control at any time and it can be used in conjunction with your current pain medications, if necessary.

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All patients do not respond the same way to spinal cord stimulation (SCS) and experiences may vary. Patients should consult a physician to understand the potential benefits and risks of treatment with SCS.

HF10 therapy statistics and competitive information are supported by this randomized clinical trial: Kapural L, Yu C, Doust MW, et al. Novel 10-kHz high-frequency therapy (HF10 therapy) is superior to traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: the SENZA-RCT randomized controlled trial. *Anesthesiology*, 2015;123:851-860.

9 OUT OF 10 PATIENTS WHO TRY HF10 THERAPY CHOOSE TO STAY WITH IT

HF10 therapy gives you the opportunity to trial a temporary system before you and your doctor decide if the permanent implant is right for you. The trial system delivers the same therapy as the implanted device. The trial period gives you and your doctor enough time to assess its effectiveness in managing your pain.

In a clinical study that allowed patients to try both HF10 therapy and traditional SCS, results showed that 9 out of 10 patients preferred HF10 therapy.

During traditional SCS procedures, the patient must be awakened from a sedated state during the procedure to help the physician locate the most beneficial position for the electrodes. HF10 therapy does not require this step. You do not have to be awakened during the procedure, so it's less disruptive to you and allows the procedure to be more predictable for the physician. The implant procedure for both the HF10 therapy trial and the permanent device is fairly quick and minimally invasive, so it may not require a hospital stay. If necessary, the system can be removed by your doctor.

PAIN FREE FOR OVER TWO YEARS.

“WHEN HF10 THERAPY FIRST STARTED WORKING, IT WAS ALMOST TOO GOOD TO BE TRUE. I WAS WAITING FOR THE CRASH, LIKE WITH THE INJECTIONS OR THE SURGERY. YOU KNOW, FEEL GOOD FOR A LITTLE WHILE, THEN TO BE IN PAIN AGAIN AND HAVE MY WORLD COME TUMBLING BACK DOWN. BUT THAT HASN'T HAPPENED AND IT'S BEEN OVER TWO YEARS NOW THAT I'VE BEEN PAIN FREE.”

STEVE, U.S. STUDY PATIENT