

NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY

Brief Summary: Product Technical Manuals and Programming Guides must be reviewed prior to use for detailed disclosure.

Indication for Use - Chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain. **Contraindications:** Diathermy. **Warnings:** Defibrillation, diathermy, electrocautery, MRI, RF ablation, & therapeutic ultrasound can result in unexpected changes in stimulation, serious patient injury or death. Rupture/piercing of neurostimulator can result in severe burns. Electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device. **Precautions:** The safety and effectiveness of this therapy has not been established for: pediatric use, pregnancy, unborn fetus, or delivery. Follow programming guidelines & precautions in product manuals. Avoid activities that stress the implanted neurostimulation system. EMI, postural changes, & other activities may cause shocking/jolting. **Adverse Events:** Undesirable change in stimulation; hematoma, epidural hemorrhage, paralysis, seroma, CSF leakage, infection, erosion, allergic response, hardware malfunction or migration, pain at implant site, loss of pain relief, chest wall stimulation, & surgical risks.

For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com.

USA Rx Only Rev 0209

For more information on Medtronic Pain Therapies visit www.TameThePain.com

www.medtronic.com

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Neurostimulation Therapy for Chronic Pain

INTRODUCTION AND NEXT STEPS

1
Introduction and
Next Steps

Grace C.

*Benefiting from Medtronic
Neurostimulation Therapy
since 2002*

REJOIN
your life



Medtronic

REJOIN *your life*



Robin P.

*Receiving Neurostimulation
Therapy since 2001*



Dayna W.

*Receiving Neurostimulation
Therapy since 2003*



Melanie S.

*Receiving Neurostimulation
Therapy since 2001*

You've experienced the limitations that chronic pain presents in your life. In the time you've been in pain, you've probably tried a number of treatments. **It's time to find out about another option that may bring much needed relief.**

In this packet you'll learn about neurostimulation therapy from Medtronic. Since FDA approval of the Medtronic system in 1984, neurostimulation therapy has helped people better manage their pain and rejoin life. It may be able to help you, too.

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LIVING WITH CHRONIC PAIN

If you or someone you love has been living with chronic pain, you know the effect it can have on a person's life. Simple activities become burdensome chores. Life goals are compromised or abandoned. Depression and isolation may set in.

For some people, pain medications provide much needed relief. For others, drugs may not adequately address the pain. Side effects from medication and increasing dosages present other challenges.

Fortunately, there is hope for relief. For many people, neurostimulation has helped manage their chronic pain and enhanced their lives. Some people have been able to reduce or even eliminate pain medications. While neurostimulation may not take away all of your pain, it has the potential to reduce your pain level and improve your ability to participate in activities you once enjoyed.

For you, success with neurostimulation may mean you can sit through a movie, take an extended car ride, work in your garden, go for a walk, or be social all with less pain.

Read on to learn more about neurostimulation therapy.

there is
hope

OVERVIEW OF NEUROSTIMULATION THERAPY

WHAT IS NEUROSTIMULATION THERAPY?

Neurostimulation therapy is a proven safe and effective therapy for managing chronic pain. Medtronic neurostimulation therapy is approved by the FDA. Pain messages are sent to the brain along nerves in your spinal cord. Neurostimulation uses mild electrical impulses to block pain signals to the brain. This means the electrical impulse from the neurostimulator reaches your brain first, before the pain signal arrives. Instead of pain, you feel a tingling sensation from the neurostimulator in the area where you experience pain.

Having a neurostimulation system implanted is also known as "long-term therapy." Throughout this brochure, the neurostimulation implant will be referred to as long-term therapy.



Grace C. with her husband, Oscar

NEUROSTIMULATION BENEFITS

Many people experience improvements in their pain symptoms and quality of life after receiving Medtronic neurostimulation therapy.

Benefits may include:

- Significant and sustained reduction in leg and back pain^{1,2,3}
- Improved ability to function and participate in activities of daily living¹
- Less oral pain medications⁴
- Proven safe and effective when used as directed
- Tested in studies worldwide^{2,3}
- Reversible and nondestructive—the therapy can be turned off or surgically removed
- You have the ability to adjust the therapy based on your pain level
- With improvements in your pain you may be able to participate in other forms of therapy to better help manage your pain

NEUROSTIMULATION RISKS

The neurostimulation implant is surgically placed under the skin. Surgical complications are possible and may include infection, pain at the site of surgery, and bleeding into the epidural space. Once the neurostimulation system is implanted, device complications may occur and include corrective surgery, jolting, lead breaking, and movement of the lead within the epidural space which may require reprogramming or surgical replacement of the leads. These events may result in uncomfortable stimulation or loss of therapy.

WHAT ADVANTAGES DOES IT OFFER OVER OTHER THERAPIES?

Neurostimulation offers advantages over other therapies for chronic pain:

- Unlike other chronic pain treatments or surgeries, you can experience neurostimulation and see if it relieves your pain before committing to the long-term therapy.
- A screening test serves as a temporary evaluation period. The screening test is much like an injection, but instead of medication being placed into the epidural space, leads are positioned and connected to an external neurostimulator (battery pack).
- Unlike oral medications that circulate throughout your entire body, neurostimulation targets the precise area where you are feeling pain.
- A neurostimulator may provide relief when other treatments—like medications or injections—have not.

HAS IT BEEN PROVEN AND IS IT COVERED BY INSURANCE?

Neurostimulation therapy from Medtronic is a proven safe and effective therapy. It is approved by the FDA and is covered by most private health insurance providers, Medicare, and most state Medicaid programs.

WHAT COULD THIS THERAPY DO FOR ME?

If you've been living with chronic pain for 6 months or more, you've probably given up some of the activities you enjoy most. Your interactions and relationships with others may have suffered.

It is possible that neurostimulation may:

- Help you rejoin life so you can get back to the activities and people that make you happiest.
- Allow you to tame the pain so you feel you're in better control of your condition.
- Reduce your need for oral medications.⁴
- Provide you with peace of mind in knowing you've selected a neurostimulator that was manufactured by Medtronic, the first company to introduce neurostimulation for chronic pain relief.
- Give you reassurance because Medtronic's neurostimulation systems have FDA approval for MRI use for head scans,* should you need one.
- Increase your confidence when you consider that more than 250,000 people worldwide have used Medtronic neurostimulation therapy to manage their chronic pain.

*Excludes Itrel® 3

WHAT YOU SHOULD KNOW

It is important that you manage your expectations of neurostimulation therapy.

Not everyone responds to neurostimulation the same way and your experience may vary. To understand the benefits and risks of neurostimulation therapy, please discuss them with your doctor. For additional safety information, please call Medtronic at 800-328-0810 and consult Medtronic's website at www.medtronic.com/chronicpain. A prescription is required.

for further info
contact

Medtronic Patient Services at
800-510-6735

Monday–Friday, 8:00 am to 5:00 pm CT

WHAT'S INVOLVED IN DECIDING ON NEUROSTIMULATION THERAPY?

Typically, there are **four steps** in deciding on neurostimulation therapy. Your doctor will advise you each step of the way.

UNDERSTAND

Begin by **understanding neurostimulation therapy**, its benefits and risks.

1

PREPARE

To prepare for the possibility of receiving neurostimulation, **you will have a screening test to see if neurostimulation can help manage your pain.** There are two important steps before the screening test. Step one is addressing any medical issues with your doctor. Step two is a psychological evaluation, which is used by your doctor and insurance company to ensure there are appropriate expectations for the trial and therapy. It is also to assist you in addressing any negative effects chronic pain has had on your mood and outlook.

2

EVALUATE

During the screening test, you and your doctor will evaluate if neurostimulation is the right treatment for you. **This is your opportunity to experience what neurostimulation feels like and to find out if your pain responds to the therapy.**

3

RECEIVE

If you have a successful screening test and your pain responds to neurostimulation, you can proceed with long-term therapy. You have had a successful screening test if you have 50%, or greater, pain relief and seen improvement in your ability to function.

4

TAKING THE NEXT STEP

Neurostimulation may be right for you if:

- Other treatment options haven't provided pain relief or have intolerable/unwanted side effects
- You don't have a serious, untreated dependence on pain medication
- You don't have medical issues that would make surgery difficult

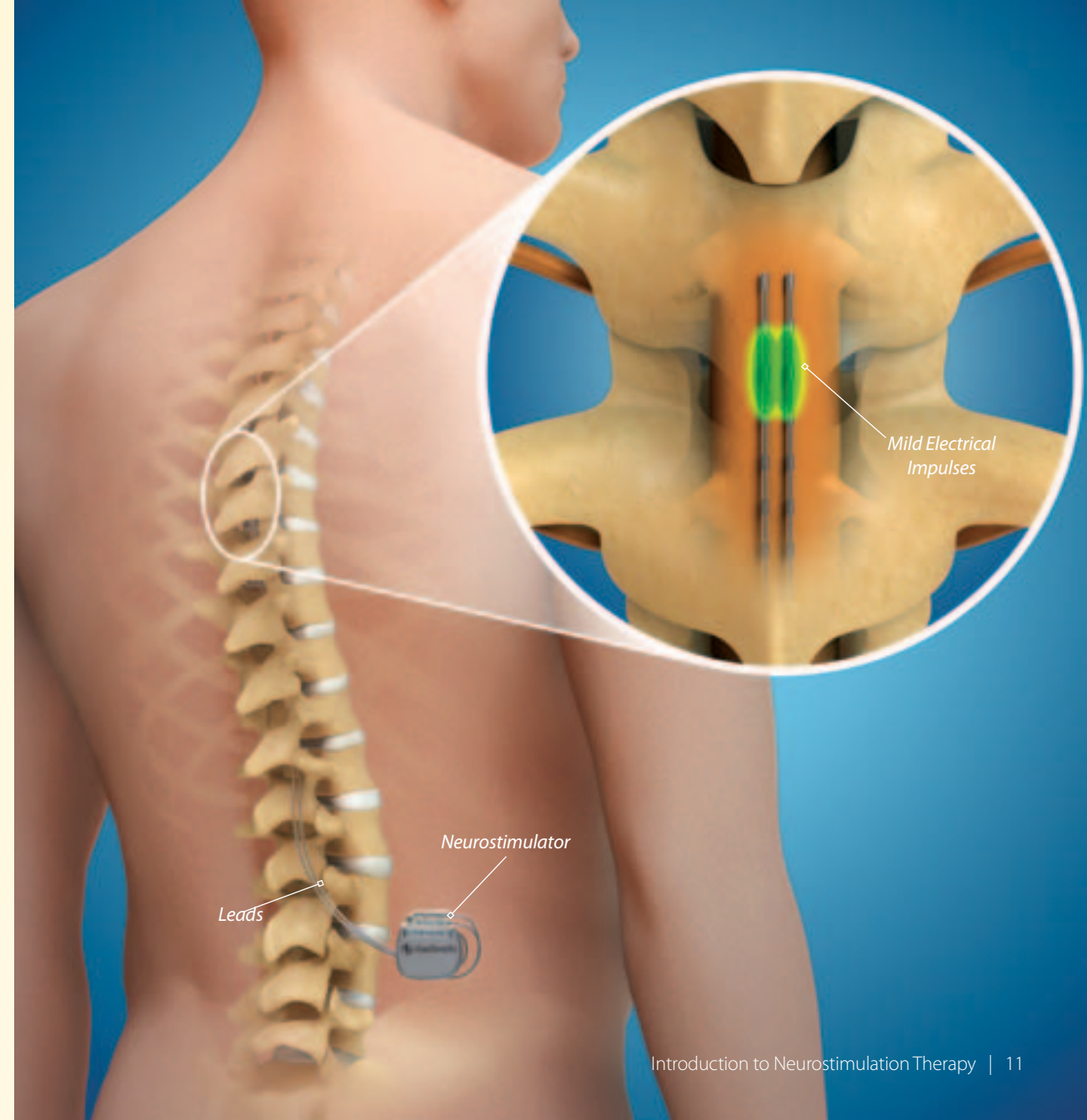
A Medtronic implantable neurostimulation system is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain.

OUTSMARTING YOUR PAIN

You can think of neurostimulation as a way to outsmart your pain.

Neurostimulation works by delivering mild electrical impulses to the spinal cord. These impulses interrupt the pain signals to your brain, replacing them with a tingling sensation that covers the specific areas where you feel pain.

Neurostimulation therapy may relieve your chronic pain so you may be able to take fewer oral pain medications.⁴

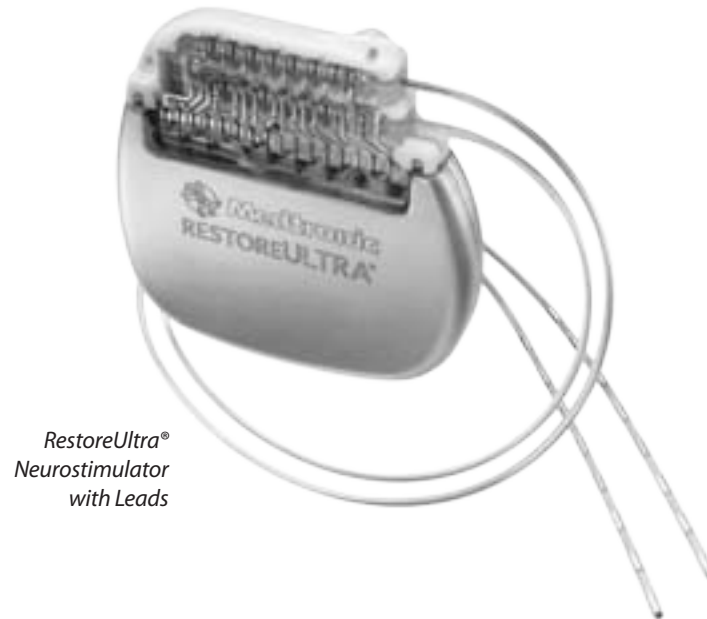


HOW DOES THE THERAPY WORK?

The neurostimulator delivers mild electrical impulses to an area near your spine. The impulses travel from the device to your spine over thin insulated medical wires called leads.

A neurostimulator:

- Is a device similar to a pacemaker.
- Is surgically implanted under the skin, typically in your abdomen or upper buttocks.
- Delivers mild electrical impulses to an area near your spine through one or more leads (insulated medical wires). The electrical impulses cause a tingling sensation in the area of your back and leg pain. So, instead of feeling pain, you'll feel a tingling sensation.



*RestoreUltra®
Neurostimulator
with Leads*

A handheld programmer that acts like a remote control allows you to:

- Adjust the strength and location of stimulation.
- Regulate different levels of stimulation at different times of the day or for various activities, such as walking, sleeping, or sitting.
- Optimize pain relief based on how your pain is changing throughout the day and your activities.

LEARNING ABOUT THE SCREENING TEST

TRY NEUROSTIMULATION TEMPORARILY WITH A SCREENING TEST

One of the benefits of neurostimulation is that a screening test allows you to try the therapy before you commit to it. The screening test is sometimes called a trial period or a temporary evaluation period. It is an opportunity for you to experience neurostimulation and see if it helps control your pain or improve your function.

During the screening test, you can:

- Assess how well the neurostimulator relieves your pain during different activities.
- Feel the tingling sensation generated by the neurostimulator to block your pain.
- Decide if you want to go on to have the long-term therapy.

YOUR TEMPORARY NEUROSTIMULATION SYSTEM

The screening test uses a temporary neurostimulation system that consists of:

- **Temporary Leads**—Thin insulated medical wires that are placed in the epidural space of your spine to deliver electrical impulses from the neurostimulator to the nerves along the spinal cord.
- **Screening Cable**—The screening cable connects the leads to the external neurostimulator.
- **External Neurostimulator**—An external device that is worn around the waist and delivers the mild electrical impulses that interrupt the pain signals. It works similar to the implanted neurostimulator. You can adjust how the therapy feels with a programmer.
- **Holder with Belt Clip**—The pouch that holds your temporary external neurostimulation system on your belt so you can go about your daily activities.
- **MyStim® Programmer**—The device that allows you to turn the device on and off and adjust stimulation levels to obtain the best possible pain relief. It works like a television remote control.

TEST STIMULATION SYSTEM



CAN YOU ADDRESS MY CONCERNS?

When considering neurostimulation therapy, it is normal to have concerns. Here are common concerns and the facts to address them.

Should I be concerned about having a foreign object in my body?

Millions of people around the world have been implanted with pacemakers, ICDs and neuromodulation devices, and most people tolerate the devices well. Medtronic performs routine testing to ensure devices are safe to be implanted in your body.

What about infection?

As with any surgical procedure, there is a risk of infection. Follow directions given by your doctor to assist in preventing infection. Contact your doctor with questions or concerns.

I'd like to wait to get this therapy until I know someone who has it.

Fortunately, you don't have to wait until you know someone before talking to a person who is living with neurostimulation therapy. The Medtronic Ambassador Program puts people like you—those who are considering the therapy—in touch with a volunteer who is living with the therapy and is interested in sharing their experience with you. **To talk with an ambassador, visit www.PainAmbassadors.com, or call 888-430-PAIN.**

I am concerned that having this therapy may inhibit some of my activities.

After you have healed from the implant procedure, you will be able to perform many activities of daily life. There are some activity restrictions, such as activities that put undue stress on the implanted components of your neurostimulation system or that include

addressing your concerns

sudden, excessive, or repetitive bending, twisting, bouncing, stretching, or lifting. Please discuss specific activities with your doctor.

I am fearful of surgery.

It is natural to feel somewhat hesitant about any type of surgery. Unlike back surgery, you will have undergone a screening test prior to having your neurostimulation system placed and will have some knowledge of your expected outcome. You can expect a shorter recovery period than with a back surgery. Talk to your doctor about what surgery may mean for you.

What if I need an MRI?

Only Medtronic neurostimulation systems for chronic pain have FDA approval for use with MRI head scans.* Approximately 25% of MRI scans are head scans.⁵ Tell the technician before having an MRI that you have a neurostimulator so the guidelines for your system can be followed.

*Excludes Itrel® 3

WHY MEDTRONIC IS THE RIGHT CHOICE

You and your doctor have your choice of companies that offer neurostimulation therapy for chronic pain. It is important that you research these companies and learn about their history with the therapy. At Medtronic, our goal is to help you rejoin your life. As the worldwide leader in medical technology, we've been working with doctors and patients around the world to develop pain therapies longer than any other medical company.

You should know:

- Neurostimulation therapy was developed by Medtronic and was first approved in 1984.
- Medtronic has transformed the lives of hundreds of thousands of people with chronic pain using neurostimulation therapy.
- More doctors trust Medtronic than any other company offering neurostimulation therapy.
- Medtronic is a worldwide leader in medical technology and the largest medical device company in the world.
- Medtronic offers the most therapeutic options available to meet your specific pain relief needs.
- Medtronic offers the widest education network for your neurostimulation system and has a presence in 120 countries worldwide. So no matter where you go, you're never far from a doctor who is familiar with your neurostimulation system.
- Medtronic neurostimulators can be implanted along with a pacemaker or ICD.
- We never stop working on better therapies to help people lead fuller, healthier lives.

We would like the opportunity to help improve your life.

Only Medtronic

has exclusive FDA approval for MRI head scans* with its neurostimulation system.

Approximately 25% of MRI scans are head scans.⁵

**Excludes Itrel® 3*

PATIENT STORIES

HOW HAS THIS THERAPY AFFECTED THE LIVES OF OTHERS LIKE ME?

People who have rejoined their life thanks in large part to Medtronic neurostimulation therapy often want to share their experiences. Here are a few of their stories.

These stories recount the experiences of three people who are receiving Medtronic neurostimulation therapy. Medtronic invited them to share their stories candidly. Please bear in mind that the experiences are specific to these particular people. Not everyone who receives neurostimulation therapy will receive the same results as the people in these stories.

Talk with your doctor to determine if neurostimulation therapy is right for you.

JACLYN'S STORY

While cheerleading in 2000, Jaclyn landed awkwardly and broke her ankle. The ankle healed, but chronic pain in the ankle and lower leg remained, limiting her ability to walk, interact with others, and sleep.

Jaclyn's primary care doctor tried a variety of treatments for the pain. Unfortunately, oral medications did not significantly reduce the pain and made her nauseous. Physical therapy provided only temporary relief.

"The pain escalated to an unbearable level," says Jaclyn. "My leg swelled, ached, and felt like it was on fire. Both my ankle and leg were sensitive to touch. Water, heat, cold— even a breeze—caused pain."



Jaclyn P.
*Benefiting from Medtronic
Neurostimulation Therapy
since 2001*

LEARNING ABOUT NEUROSTIMULATION

After a year with the pain, Jaclyn's primary care doctor referred her to a pain management physician. She was diagnosed with complex regional pain syndrome (CRPS). Her doctor thought the pain might respond to neurostimulation therapy from Medtronic.

“I couldn't live a normal life without my neurostimulation system.”
—Jaclyn P.

To see if neurostimulation could help control Jaclyn's pain, she underwent a screening test.

“During the screening test, I felt a comforting and soothing tingling sensation in place of the pain,” Jaclyn recalls. “This confirmed for my doctor that I was a candidate for the therapy.”

LIVING A FULL LIFE

At the time she was referred to the pain management doctor, Jaclyn had lost weight, was not eating, and was experiencing sleep deprivation. Today, she's back to living a full life. Looking back, she wonders if she might have avoided those symptoms had she been referred to the pain management doctor and had the benefit of the neurostimulation sooner.

“I am able to sleep, hike, bike, and walk my dog. I couldn't live a normal life without my neurostimulation system.”


DAVID'S STORY

For 10 months, David noticed that it was getting harder to do his job as a frozen foods sales representative. He had trouble walking because he was losing feeling in his foot. Then one day in October 2008, he couldn't get out of bed.

“I had pain in my back, hip, knee and numbness in my lower left leg and foot,” David remembers. “Once I got out of bed, it got worse.”

A visit to the chiropractor didn't provide relief, nor did an injection from his doctor. In December 2008, David had a laminectomy and a laminotomy on the lower lumbar area of his spine. While recovering in the hospital, he lost more feeling his lower extremities resulting in another surgery to relieve the paralysis. Physical therapy helped David regain his mobility, but the numbness in his left foot persisted.

“I thought it would go away with time, but it became progressively worse,” David says. Walking became more difficult because of chronic pain in his back, hip and leg. His mobility diminished along with the feeling in his left leg. He began using crutches and eventually a wheelchair. Anti-inflammatories and epidural shots took the edge off but didn't control the pain.

A man with a shaved head, wearing a light green polo shirt and khaki pants, is sitting outdoors and playing a large silver tuba. The background is a lush green field with trees. The lighting is bright and natural, suggesting a sunny day.

David W.
*Benefiting from Medtronic
Neurostimulation
Therapy since 2009*

"I could no longer work and I couldn't do normal things anymore like go to the store or get gas for my car," he remembers. "It wasn't a good time for me, my wife or children."

LEARNING ABOUT NEUROSTIMULATION

David's doctor thought scar tissue in his back would compromise his chances for success with another surgery. He recommended neurostimulation therapy from Medtronic. The first step was for David to have a screening test to see if his pain would respond to the therapy.

"When they turned on the neurostimulation system, it felt a little like the tingling sensation," David says. "It felt like it reached every part of my pain that needed it. When they turned the system off, I felt deflated. I didn't want the screening test to end!"

Four weeks later, David had the neurostimulation system surgically placed.

A BETTER LIFE

David no longer needs pain medications. Occasionally, he takes ibuprofen for his arthritis.

"I can walk again and I can spend more quality time with my family," David says. "I work out about 3 days a week and try to walk a few miles every day. It depends on how I'm feeling—some days I have to read my body."

For David, controlling his pain has resulted in an improved attitude. "My friends and family tell me that I'm returning to my old self. With an improved attitude and less pain, I feel like I'm contributing again."

GRACE'S STORY

In 1995, Grace was serving in the Air National Guard. One afternoon, while preparing for an inspection, she was moving equipment when she strained her back. Barely able walk, she learned she had a herniated disc, high grade stenosis and spondylothesis.

Multiple surgeries, including a fusion, followed. Unfortunately Grace still had pain and spasms after back surgery. She was diagnosed with failed back syndrome. "I had paralyzing pain in my back," Grace recalls. "It was like a domino effect in that it started in my lower back and then spread to my neck, down to my hips, and into my legs and feet."

Grace was medically discharged from the Air National Guard, gave up her profession as an English instructor, and stopped working on her Master's degree. She stopped playing softball and coaching her children's Little League teams. Her pain fluctuated between 7-10 on the pain scale.

"My life just stopped for 12 years," she says. "I couldn't clean my house, do the laundry, or even get groceries by myself. My husband had to help me with everything. I was depressed and angry during those years."

To control her pain, Grace tried a TENS unit, acupuncture, muscle relaxers, physical therapy, trigger point injections, epidural injections, anti inflammatories, and oral pain medications.

LEARNING ABOUT NEUROSTIMULATION

Grace's doctor thought neurostimulation therapy from Medtronic might help her. She underwent a screening test to see if the therapy would help control her pain.

"It was amazing. When they turned on the neurostimulator, I could immediately feel the stimulation and I knew it would work for me," she says.

In 2002, Grace had the neurostimulation system surgically placed. In 2007, Grace experienced a complication where her lead moved and it had to be replaced.



Grace C.

*Benefiting from Medtronic
Neurostimulation Therapy
since 2002*

A GOOD AND SATISFYING LIFE

Today, Grace is an avid bicyclist and she teaches indoor cycling. “With the neurostimulator, I am able to increase my strength and be more active,” she says.

Most important, she is back to enjoying life with her family. She participates in her children’s athletics and her husband no longer has to care for her and handle all of the household tasks.

“We can have fun again and my family isn’t always feeling bad for me,” she says. “I may not have the life I used to, but it is an equally good and satisfying life. There is hope beyond the pain.”

The neurostimulation implant is surgically placed under the skin. Surgical complications are possible and may include infection, pain at the site of surgery and bleeding into the epidural space. Once the neurostimulation system is implanted, device complications may occur and include corrective surgery, jolting, leads breaking, and movement of the leads within the epidural space which may require reprogramming or surgical replacement of the leads. These events may result in uncomfortable stimulation or loss of therapy.

MEDTRONIC AMBASSADOR PROGRAM

TALK WITH SOMEONE WHO UNDERSTANDS

We understand you may have questions that can only be answered by someone who has had a similar experience. Let us help you make that connection.

The Medtronic Ambassador Program is for people considering the therapy. The program puts you in touch with a volunteer who is interested in sharing their experience with neurostimulation therapy.

Talking to someone who has neurostimulation is one more way you can determine if this therapy is right for you.

To request that a volunteer ambassador contact you, visit www.PainAmbassadors.com or call Medtronic at: 888-430-PAIN (7246). Phones are staffed from 8:00 am to 5:00 pm central time.

You will be asked a few questions to help pair you with an ambassador whose situation is similar to your own. Then your name and phone number will be shared with your ambassador.

Common questions for an ambassador include:

- When did you begin receiving neurostimulation therapy?
- What did you experience during the screening test?
- How has neurostimulation therapy changed your life?

Please note that Ambassador Program is for individuals who are considering neurostimulation and not for those who already have the therapy.

YOUR NEXT STEP

Now that you know more about neurostimulation, consider having a screening test to see if the therapy will help relieve the pain you've been enduring.

Remember, the screening test:

- Is a temporary evaluation period
- Lets you assess how well the neurostimulation relieves your pain during different activities
- Gives you the chance to experience the tingling sensation generated by the neurostimulator
- Allows you and your doctor the opportunity to see if neurostimulation is right for you
- Helps you decide if you want to move forward with long-term therapy

If you would like to have a screening test, talk to your doctor.

improve
your life

LEARN MORE

Now that you've reviewed this brochure, we encourage you to take these next steps to learn more about Medtronic neurostimulation therapy.

- **View the enclosed DVD.**
- **Discuss the information with your doctor.**
- **Visit www.TameThePain.com**
- **Request to talk with a volunteer ambassador about his or her experience with neurostimulation therapy. Visit www.PainAmbassadors.com or call 888-430-7246.**

REFERENCES

1. Kumar K, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomized controlled trial in patients with failed back surgery syndrome. *Pain*. 2007;132:179-188.
2. Kumar K, Taylor RS, Jacques L, et al. The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. *Neurosurgery*. 2008;63:762-770.
3. Turner JA, Loseser JD, Deyo RA, Sanders SB. Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: a systematic review of effectiveness and complications. *Pain*. 2004;180:137-147.
4. Ohnmeiss DD, Rashbaum RF, Bogdanffy GM. Prospective outcome evaluation of spinal cord stimulation in patients with intractable leg pain. *Spine*. 1996;21:1344-1350.
5. IMV MRI market benchmark report 2007.

A man with a mustache, wearing a green polo shirt and blue jeans, is fishing from a wooden pier. He is holding a fishing rod and reel, and the background shows trees with yellow and orange autumn leaves. A green semi-transparent box is overlaid on the right side of the image, containing text.

*“I can go out fishing
with my son again.”*

—Jerry L.
Benefiting from Neurostimulation
Therapy since 2008