LEGAL DISCLOSURES

The Boston Scientific Spinal Cord Stimulator Systems are restricted to sale, distribution or use by or on the order of a physician.

Indications for Use

Boston Scientific’s Spinal Cord Stimulator systems (SCS) are indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain and leg pain.

Contraindications

The Spinal Cord Stimulator systems are not for patients who are unable to operate the system, have failed trial stimulation by failing to receive effective pain relief from surgical implant of an appropriate nerve stimulator, or have failed trial stimulation by failing to be on the order of a physician. The system is also contraindicated for patients who are pregnant.

Patients implanted with the Precision™ Plus or Precision Spectra™ Spinal Cord Stimulator System with ImageReady™ MRI Technology are “MR Conditional” only when exposed to the MRI environment under the specific conditions defined in the ImageReady MRI Guidelines for Precision Spectra Spinal Cord Stimulator System manual.

Warnings

Patients implanted with the Precision™ Plus or Precision Spectra™ Spinal Cord Stimulator System without ImageReady™ MRI Technology should not be exposed to Magnetic Resonance Imaging (MRI). Exposure to MRI may result in dislodgement of the stimulator or leads, heating of the stimulator, severe damage to the stimulator electronics and an uncomfortable or jolting sensation.

As a Spinal Cord Stimulation patient, you should not have diathermy as either a treatment for a medical condition or as part of a surgical procedure. Strong electromagnetic fields, such as power generators or theft detection systems, can potentially turn the stimulator off, or cause uncomfortable jolting stimulation. The system should not be charged while sleeping. The Spinal Cord Stimulator system may interfere with the operation of implanted sensing stimulators such as pacemakers or implanted cardiac defibrillators. Advise your physician that you have a Spinal Cord Stimulator before going through with other implantable device therapies so that medical decisions can be made and appropriate safety measures taken. Patients should not operate motorized vehicles or potentially dangerous machinery with therapeutic stimulation switched “on.”

Your doctor may be able to provide additional information on the Boston Scientific Spinal Cord Stimulator System. For a copy of the Boston Scientific Spinal Cord Stimulator Systems Patient Handbook, including the indications for use, contraindications, warnings, precautions, and side effects, call 866.360.4747 or visit ControlYourPain.com.

Caution

Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Managing Chronic Pain with Spinal Cord Stimulation Therapy

Get back the little things that pain has taken away.
Managing Chronic Pain with Spinal Cord Stimulation Therapy
In the sunny dawn of each bright, new day, Meghann faced a dark reality: chronic, unrelenting, often unbearable pain.

Yet the excruciating ache in her lower back and leg was nothing compared to the hopeless, helpless, empty feeling in the pit of her stomach: a void created by the realization that this—after numerous surgeries and countless medications—is how she’d likely spend the rest of her life.

At Last, Chronic Pain Patients are Facing a Brighter Future
Smoothing the Jagged Edges of Pain

The Boston Scientific SCS Systems are indicated for patients with chronic pain of the trunk and/or limbs (low back and legs). The systems, which feature our revolutionary SmoothWave™ Technology, work to interrupt pain impulses before they reach the brain, replacing them with a smooth, soothing feeling.

Unlike all other spinal cord stimulation systems, Precision Spectra™ with SmoothWave Technology utilizes 32 independently programmed power sources designed to tailor stimulation to target your unique needs. With twice the stimulating contacts of any other SCS system, Precision Spectra is designed to cover more pain.

If you have chronic pain, there’s no need to face it alone. Put Boston Scientific on your side.

Precision Spectra™ SCS System
This new SCS System features a discreet, easy-to-use remote that lets you control when, where and how much pain relief you receive.

Spinal Cord Stimulation (SCS) Therapy by Boston Scientific

Today, thanks to the compassionate foresight of her doctor and the remarkable SmoothWave™ Technology of Boston Scientific, Meghann has joined over 400,000 people around the world no longer held captive by the physical and emotional ravages of chronic pain.

With the Boston Scientific SCS System, managing Meghann’s pain is right in the palm of her hand. Empowering her to reclaim the life she once lived. A life bustling with normal daily activities. The rewards of work. The joy of play. Loved ones. Laughter. And so much more.

If you have chronic pain, there’s no need to face it alone. Put Boston Scientific on your side.
If you’re in the discouraging, dispiriting grip of chronic pain, we’d like to have a word with you:

“Hope.”

In this booklet and accompanying DVD, you’ll discover a safe and effective technological advancement that has helped work miracles for hundreds of thousands of chronic pain sufferers all across the globe—SCS therapy has been around for more than four decades.

Approved by the U.S. Food and Drug Administration for adults with chronic intractable pain of the trunk and/or limbs (low back and legs), the Precision Spectra™ and Precision™ Plus SCS Systems with SmoothWave™ Technology offer proven pain management.

At the same time, it gives you something just as important: real hope for a better tomorrow.

Mike’s Miracle

“I liked the idea of being in control again. I’d already been stripped of my career, I was financially ruined and I wasn’t functioning as a husband and a father. After being implanted with the Boston Scientific SCS System, I felt my life was a miracle.”

Mike Roman
Chronic Pain Patient
There’s no dancing around the fact that chronic pain management is a vexing, complicated challenge. So in designing Precision Spectra™ SCS Therapy with SmoothWave™ Technology, the medical minds of Boston Scientific decided to start with a simple, basic premise:

Since pain is carried by electrical nerve impulses along the spinal cord to the brain, intervening in the nervous system’s impulse flow is the key to managing pain. Upon that firm base of knowledge, Boston Scientific SCS Therapy was born.

Pain signals travel along nerve fibers through the spinal cord to the brain.  

Life in Full Bloom

“\(\text{I can do a lot of things, like tend to my orchids, go to the gym and go dancing. I have a full life now.}\)“

Dick B.
Chronic Pain Patient
How SCS Works

A small pulse generator 2 and insulated wires 3 are implanted into the body.

Directed by an external remote control, electrical impulses from the pulse generator mask pain signals as they travel to the brain 4 —where they’re perceived as a gentle, tingling feeling called paresthesia. 5

Result: a soothing, smoothing sensation. All without major surgery.
Reclaiming Control of Your Life Can Start by Getting the Facts

Now that you know the facts, talk to your doctor to see if Precision Spectra™ SCS Therapy with SmoothWave™ Technology can help you manage your chronic pain—and regain your healthy life.

SCS can work where other therapies haven’t
SCS can help manage intractable pain of the trunk and/or limbs (low back and legs)—even when other therapies have failed.

You can “test drive” SCS first
If your doctor recommends SCS for your pain condition, you can try out a temporary system before final implantation.

SCS is reversible
Even though your leads are surgically implanted, they can be disengaged or removed by your doctor, as needed.

Medications can work with SCS
While SCS itself does not require medication to block pain signals, it can be used in conjunction with pharmaceuticals, if necessary.

Most major insurers cover SCS
SCS is covered by most health insurance plans, including Medicare.

SCS is generally considered successful if your pain is reduced by 50 percent, if you are able to get back to your daily activities, if your need for pain medication is reduced and/or if you’re able to relax and sleep better.

Now that you know the facts, talk to your doctor to see if Precision Spectra™ SCS Therapy with SmoothWave™ Technology can help you manage your chronic pain—and regain your healthy life.

Reigning Over Pain
"After my implant of the Boston Scientific SCS System, I can now manage my pain. My pain no longer manages me.”
Robert C., Chronic Pain Patient

"After my implant of the Boston Scientific SCS System, I can now manage my pain. My pain no longer manages me.”
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You’ve had your hopes raised. You’ve had your hopes dashed. If you’re like many chronic pain patients, you’ve tried a number of therapies, surgeries and medication in your quest to manage the problem at hand—only to be disappointed.

At Boston Scientific, we understand that the prospect of trying yet another chronic pain management therapy can be stressful. With Precision Spectra™, you can try SCS therapy for a few days before committing to it over the long term.

The Boston Scientific Test Drive

Once you’ve spoken to your Pain Management Specialist about SCS, you’re ready to test drive Precision Spectra. It’s your chance to experience firsthand how advanced SmoothWave™ Technology can truly make your life smoother.

In preparation, your Pain Management Specialist will place temporary leads into your back. This is usually performed as an outpatient procedure with sedation and local anesthesia. Once placed, these leads are connected to an External Trial Stimulator worn on a belt for about two weeks. As you experience the stimulator in operation, you’ll learn the extent to which Precision Spectra with SmoothWave Technology can help control your pain and enhance your daily life.

If Precision Spectra performs up to your expectations, it can be implanted permanently. If not, the leads can be removed.

“Absolutely amazing. After getting the trial, the first thing we did was take a walk in the woods. I just couldn’t believe something so simple could help so much!”

Sara W.
Chronic Pain Patient

Walking on Sunshine
A Beautiful, New Life Begins with 5 Little Steps:

1) Read this booklet, watch the enclosed DVD and ask your Pain Management Specialist if Precision Spectra™ is right for you.

2) Visit ControlYourPain.com to learn more about SCS Therapy.

3) Visit ControlYourPain.com/Ambassador or call 800.819.4727 to connect with a patient who has benefited from SCS Therapy.

4) Visit RaceAgainstPain.com to connect with others living with chronic pain.

5) Visit CYPEvents.com to see if a “Control Your Pain” educational event is available in your area.

A Beautiful Life

“Before, I had trouble sitting at my desk in school. The pain was too much. I had to stand up in the back of the classroom. Now, with SCS, I go to school with confidence, with more self-esteem. It can change your life and really make it beautiful.”

Susan M.
Chronic Pain Patient
Q: Is spinal cord stimulation safe?
Yes, spinal cord stimulation has been proven safe and effective and has been in use for decades. Over 400,000 people worldwide have been successfully treated with SCS therapy. You should review the risks of SCS with your physician.

Q: Will I be totally pain-free with SCS?
People differ in the amount of pain relief they receive with SCS therapy. Many people experience a reduction in pain sensations. The trial procedure will help you determine the amount of relief you may receive.

Q: Will SCS allow me to be free of pain medications?
For some patients, SCS works well enough that pain medications are no longer needed. For others, it can mean a reduction in the amount of pain medications they need. Always consult your doctor before changing your dosage.

Q: Will my insurance cover SCS Therapy?
Many health plans and insurance companies cover the cost of SCS therapy. Your clinic or doctor will need to get approval first. Our customer service team can help you understand what your insurance company does and does not cover.

Q: When can I resume my usual activity?
For several weeks after the procedure you will be asked to restrict your physical activity. Once that period is over, Precision Spectra™ is designed to help you lead a healthy and active lifestyle. However, you should always consult your doctor before resuming activity after surgery or before engaging in physical activities.

Painful Questions Soothing Answers

“Instead of having a grinding, burning sensation going through me, I’ve got this nice, comforting feeling. When I first turned the stimulator on, it felt like a weight was lifted off me, it felt so good! I felt like giving this a try was the right thing to do. I’m sure glad I did.”

Meghann D, Chronic Pain Patient

1) Data on File
Q: Are there risks associated with SCS?
As with any surgical procedure, there are risks. Please discuss these risks with your physician and review the back cover of this brochure.

Q: Can I actually control the stimulation therapy?
Yes, the cordless remote control allows you to turn stimulation on and off, increase and decrease the level of stimulation and target different pain areas using settings or programs designed specifically for you.

Q: Do I use my SCS system 24 hours a day?
It’s up to you. Precision Spectra™ is designed for 24-hour-a-day use, should you wish. However, there are a few limitations, which your physician can describe.

Q: How convenient is it to recharge the implant battery?
Recharging the implant battery is designed to be convenient and simple. The charger is lightweight, cordless and portable, so you can charge on the go. Either an adhesive patch or soft cloth belt (included with the charger) can be used to recharge.

Q: Will I feel the implant?
Is it visible to others?
The implant features a contoured oval shape and is small in size. Your doctor can position it in the most comfortable and convenient location in your body. While patients often report that they can feel the unit by pressing on their skin, in most cases it is not visible to others.

Q: Can I get diagnostic imaging with this system?
SCS patients have many imaging options. Commonly used methods such as X-Rays, CT Scans, PET Scans and Ultrasounds can image many different parts of the body, including soft tissue. In addition, the Precision Spectra System allows for MRI scans of the head for patients who meet the eligibility requirements. SCS systems have varying limitations and conditions related to MRI scans. Talk to your doctor to find out which option is right for you.
In the treatment of chronic pain, just two factors are important: What works. And what doesn’t.

If surgical and pharmaceutical options haven’t worked for you, fortunately you have a viable alternative: spinal cord stimulation.

It’s an effective, proven therapy that helps mitigate your pain, putting you in control while improving your quality of life. And the information you need is right at hand.

“A New Equation: You Minus Pain

“I went to my trial with a nervous, skeptical and anxious mindset as I didn’t want to endure another disappointment. My first reaction was cautious but after only a few hours, I found myself in a state of disbelief…I could actually function!”

Leah M.
Chronic Pain Patient

Visit ControlYourPain.com and ask your Pain Management Specialist if SCS Therapy is right for you.