

# WaveWriter Alpha™

## Spinal Cord Stimulator System



### The Next Era of Personalization

WaveWriter Alpha™ provides uncompromised and personalized solutions with a comprehensive portfolio, advanced therapies and a suite of digital solutions for you, your patients and your practice.

[READY TO TRY ALPHA?](#)

### Explore

[ImageReady™ MRI Portfolio](#) ▾

[Advanced Therapies: FAST™ And Contour™](#) ▾

[Cognita™ Digital Solutions](#) ▾

[Features & Ordering Information](#) ▾

[Reimbursement](#) ▾

[Resources For You & Your Patients](#) ▾

## ImageReady™ MRI Portfolio

### Four Systems. Zero Compromise.

With rechargeable and non-rechargeable 16 and 32 contact options, WaveWriter Alpha™ offers the largest portfolio in SCS with Full-body MRI\* access.



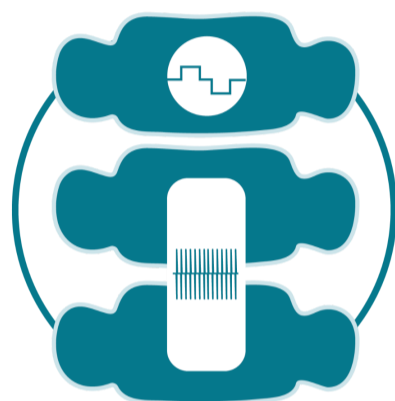


### ImageReady™ MRI

leads

- Bluetooth-enabled for broader connectivity options

## Advanced Therapies: FAST™ and Contour™



### FAST™ | Contour™

Boston Scientific advanced the science of SCS by introducing Combination Therapy - the ability to engage multiple mechanisms of action simultaneously. We have taken that advancement a step further by targeting a new, distinct SCS mechanism of action with FAST™.

[Learn More](#) ▼

## Cognita™ Digital Solutions



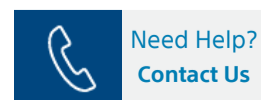
### Cognita™ Solutions

Boston Scientific is invested in enhancing your impact in the pain community with Cognita™ – a comprehensive digital solution that helps you to identify, manage, and maintain patients throughout the pain management journey.

#### IDENTIFY

- Pain.com to increase patient awareness and locate local pain management physicians
- PatientFinder helps you understand local referral trends
- mySCS App to educate patients early in the process

#### MANAGE



**MAINTAIN**

- mySCS app to stay connected with patients post-implant
- Patient Review to assess overall patient outcomes over time
- Bluetooth connectivity to enable future patient outcome visibility
- To get started, contact your Boston Scientific representative to schedule your MBI consultation.

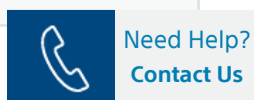


Receive personalized resources >

Show Less ^

**Features & Ordering Information**

FEATURE	WAVEWRITER ALPHA™	WAVEWRITER ALPHA™ 16	WAVEWRITER ALPHA™ PRIME	WAVEWRITER ALPHA™ PRIME 16
Power Sources	32	16	32	16
Volume	21.6cc	20.1cc	36.6cc	34.9cc
Thickness	10.7mm		11.6mm	
Battery Type	Rechargeable		Non-Rechargeable	
Battery Capacity	200mAh		7Ah	
Wireless Recharging	Yes		N/A	
Wireless Remote	Yes			
Remote Range	10 Feet			
Bluetooth Enabled	Yes			
MRI Conditionality	Full Body			



FDA Labeling	FDA approved for both paresthesia and paresthesia-free therapies
Advanced Paresthesia and Paresthesia-Free Therapies	FAST™, Contour™, Illumina 3D™ Standard Rate, High Rate 3D, MicroBurst 3D, Burst 3D, Prism™ Targeting
Simultaneous Combination Therapy	Yes
Amplitude	0-25.5mA
Rate	2-1200Hz
Pulse Width	20-1000µs
Upgradeable	Yes

MODEL NUMBER	UPN	DESCRIPTION
SC-1416	M365SC14160	WaveWriter Alpha™ Prime 16 Implantable Pulse Generator Kit
SC-1432	M365SC14320	WaveWriter Alpha™ Prime Implantable Pulse Generator Kit
SC-1216	M365SC12160	WaveWriter Alpha™ 16 Implantable Pulse Generator Kit
SC1232	M365SC12320	WaveWriter Alpha™ Implantable Pulse Generator Kit
SC-5572-1	M365SC557210	FreeLink™ Remote Control Kit
SC-6500-72	M365SC6500720	WaveWriter Alpha™ Patient Trial Kit
SC-8436-50	M36SC8436500	CoverEdge™ MRI 50cm, 32 Contact, 4x8 Surgical Lead Kit
SC-8436-70	M36SC8436700	CoverEdge™ MRI 70cm, 32 Contact, 4x8 Surgical Lead Kit
SC8452-50	M365SC8452500	CoverEdge™ X MRI 50cm, 32 Contact, 4x8 Surgical Lead Kit
SC8452-70	M365SC8452700	CoverEdge™ X MRI 70cm, 32 Contact, 4x8 Surgical Lead Kit

## Reimbursement

Call the Neuromodulation Reimbursement Help Desk at 1-866-287-0778 or access our [reimbursement resources](#) to get up-to-date educational, coverage, coding, payment and product information. Access our guides to easily look up CPT codes, ICD-10 codes, physician RVUs, and Medicare national average reimbursement rates for SCS.



[AlphaSCS.com >](#)

[Directions for Use >](#)

[Indications, Safety, and Warnings >](#)


[Join Upcoming Alpha Events](#)

[Contact Customer Support](#)

[Receive the Latest Updates](#)

Boston Scientific offers a wide range of pain therapy solutions. Make an appointment to talk to your representative about how they can tailor a pain management solution that's right for your patients and your practice.

[Learn More >](#)

 \*The WaveWriter Alpha™ SCS System provides safe access to full-body MRI scans when used with specific components and the patient is exposed to the MRI environment under the defined conditions in the ImageReady™ MRI Full Body Guidelines for WaveWriter Alpha and WaveWriter Alpha Prime Spinal Cord Stimulator System.

Subperception stimulation has been demonstrated to be safe and effective in patients who have been treated successfully with conventional, paresthesia-inducing stimulation for at least six months. Full stimulation parameter ranges and options for both paresthesia based and subperception therapy are available for clinician's use throughout the patient's experience and treatment with SCS.



**Boston Scientific is dedicated to transforming lives through innovative medical solutions that improve the health of patients around the world.**

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WaveWriter Alpha™ SCS

# Cognita™ Solutions

Partnership Made Personal.



Overview

Unified Portfolio

Advanced Therapies

Cognita Solutions

[Medical Specialties](#) > [Pain Management](#) > [WaveWriter Alpha™ SCS Solution Overview](#) > Cognita Solutions

## The Right Tools to Help Meet Your Goals



**Cognita Solutions: Partnership Made Personal**

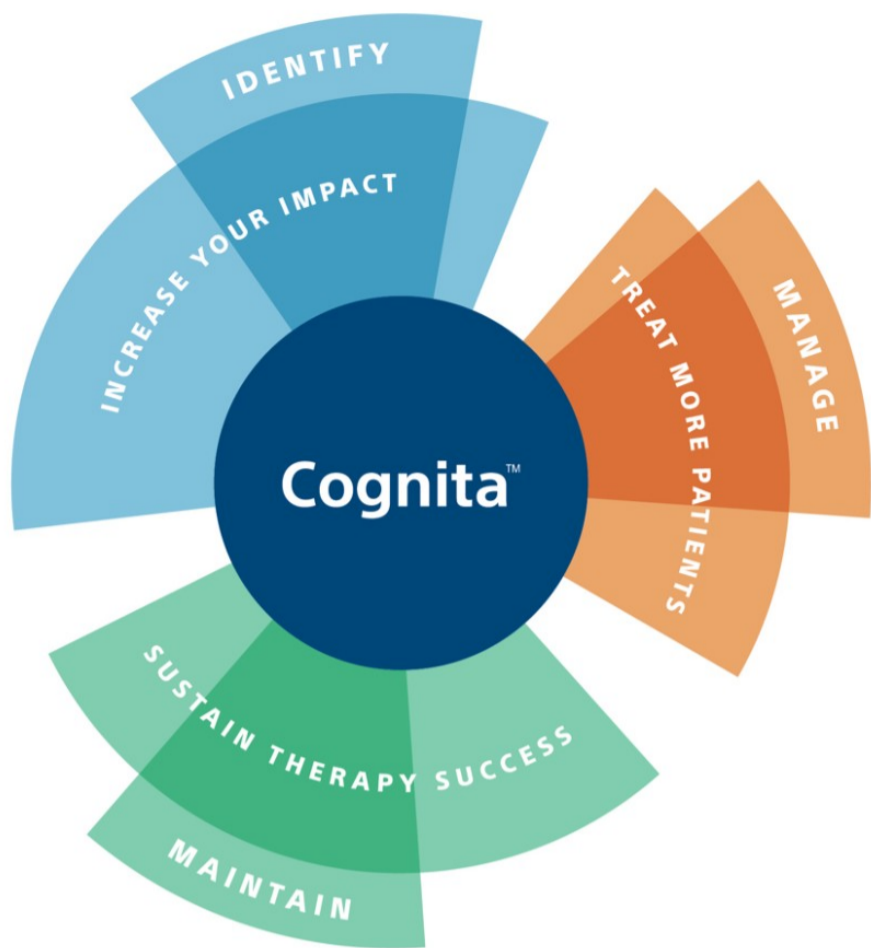
Boston Scientific is invested in growing your impact with Cognita, a comprehensive solution that helps you to identify, manage and maintain patients throughout the spinal cord stimulation pain management journey.

### Identify: Increase Your Impact

- **Pain.com** to increase patient awareness and locate local pain management physicians
- **PatientFinder** to help you understand the local pain community needs
- **mySCS App** to educate patients early in the process

### Manage: Treat more patients





denials

- **Physician Portal** for visibility on patient status and progress

### Maintain: Sustain therapy success

- **mySCS app** to stay connected with patients post-implant
- **The Patient Review** to help you track outcomes over time
- **Bluetooth®-Enabled** for broader connectivity options

Contact us to learn about these tools and more >

### Partnership Made Personal

Success in pain management goes beyond the device and therapy. We help identify market insights and strategies for your local market based on your needs to expand patient outreach, maximize practice efficiency and sustain therapy outcomes.

Request a meeting



Market and Business Insights (MBI)

### View Product Details

Find information on features, specs, indications, reimbursement information, ordering information and more.



📞 Need Help? Contact Us



### Subscribe for Updates

Receive timely access to major announcements, opportunities to connect with your peers through educational events and useful tools for you to help more patients.

[Sign up](#)

### Ready to Talk to Someone about Alpha?

Have us contact you to learn more about WaveWriter Alpha and other pain management innovations and implanted pain stimulators.

[Request a rep](#)

### Pain.com: Chronic Pain Educare for Patients

Do your patients need educational resources about chronic pain? Direct them to our pain.com website, where they can learn about implanted spinal cord stimulation devices and other treatment options.

[Share resources](#)

## Get Customer Support

[Contact Us](#)

## A Broad Pain Portfolio

### [LSS Treatment](#)

See how The Vertiflex™ Procedure<sup>†</sup> is setting the standard of care for lumbar spinal stenosis (LSS).

<sup>†</sup> Superior™ Indirect Decompression System

The Bluetooth® word mark and logos are registered trademarks owned by the Bluetooth SIG, Inc. and any use of such marks by Boston Scientific Neuromodulation Corporation is under license.

SCS Indications for Use: The Boston Scientific Spinal Cord Stimulator Systems 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 the following: failed back surgery syndrome, Complex Regional Pain Syndrome (CRPS) Types I and II, intractable low back pain and leg pain. Associated conditions and etiologies may be: radicular pain syndrome, radiculopathies resulting in pain secondary to failed back syndrome or herniated disc, epidural fibrosis, degenerative disc disease (herniated disc pain refractory to conservative and surgical interventions), arachnoiditis, multiple back surgeries. Contraindications, warnings, precautions, side effects. The SCS Systems are contraindicated for patients who: are unable to operate the SCS System, have failed trial stimulation by failing to receive effective pain relief, are poor surgical risks, or are pregnant. Refer to the Instructions for Use provided with the SCS System or Pain.com for potential adverse effects, warnings, and precautions prior to using this product.

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

IDS Indications for Use: The Superior™ Indirect Decompression System (IDS) is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, having radiographic evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. The Superior™ Interspinous Spacer is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, with or without back pain, who have undergone at least 6 months of non-operative treatment. The Superior Interspinous Spacer may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated at no more than two levels, from L1 to L5. Contraindications, warnings, precautions, side effects. The Superior Indirect Decompression System (IDS) is contraindicated for patients who: have spinal anatomy that prevent implantation of the device or cause the device to be unstable in situ (i.e., degenerative spondylolisthesis greater than grade 1), Cauda equina syndrome, or prior decompression or fusion at the index level. Refer to the Instructions for Use provided on [www.vertiflex.com](http://www.vertiflex.com) for additional Indications for Use, contraindications information and potential adverse effects, warnings, and precautions prior to using this product.

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

RF Indications for Use: The Boston Scientific Radiofrequency Generators, associated Radiofrequency Lesion Probes and RF Cannula are indicated for use in procedures to create radiofrequency lesions.



Need Help?  
[Contact Us](#)

may damage them. For appropriate guidance, consult the instructions for use for these active devices.  
Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.



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[Pain.com \(/en.html\)](#) [Understand Your Pain \(/en/understand-your-pain.html\)](#) [Find Your Relief \(/en/personal-support-resources/tools-you-can-use/personal-pain-relief-evaluation.html\)](#)

# Welcome to Relief

Explore Solutions for Your Relief ([/en/chronic-pain-solutions.html](#))

See Evidence of Real Relief ([/en/evidence-of-relief.html](#))

Get Personal Support and Resources ([/en/personal-support-resources.html](#))

You're in the right place for personal pain relief.

You'll discover how our solutions work, what makes them effective, and how others found the answer in our therapies.

Get a personalized pain relief recommendation

Take our short quiz and receive recommended treatment options and the chance to speak to a pain education specialist.



Question 1 / 8

Have you been **suffering from pain** for **more than 6 months?**

YES

NO

Find what you're searching for faster

I need help understanding what's

Nothing has worked well to relieve my pain.

You're looking for relief. We're here to help. Part of that is ensuring you're informed and prepared at every step.

[Find a Pain Doctor](#)

[Personal Support Resources](#)

[Tools you can use](#)

[Find a Pain Doctor](#)

contributing to

my pain.

What other

options do

I have?

Here are a few shortcuts that may prove helpful. →

[About Pain.com](#)

[Search](#)

I would like to see proof that your solutions may work.

[Search](#)

I currently use a Boston Scientific relief solution and need more info.

[Pain.com](#)

[Understand Your Pain](#)

[Find Your Relief](#)



[Explore Solutions for Your Relief](#)

[See Evidence of Real Relief](#)

[Get Personal Support and Resources](#)

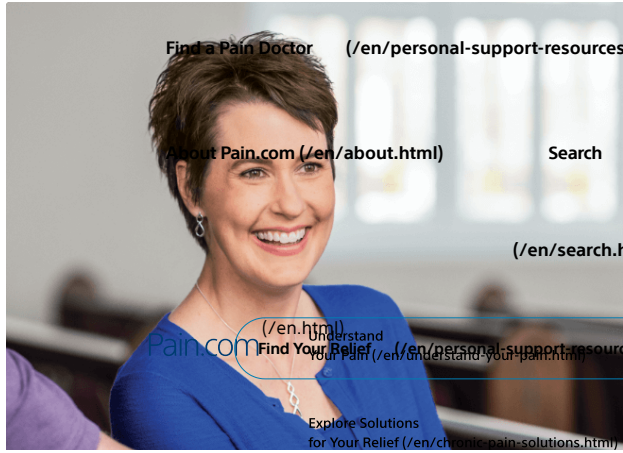


*"Pain is like a living thing. It can change in different ways...but so can your stimulator."*  
— Chris

*"My leg doesn't bother me anymore. That's what I'm really happy about."*  
— Shirley



(<https://www.bostonscientific.com/>)



# Your pain is unique

No one knows your pain better than you. Help us understand what you're experiencing so we can guide you to the right information

See Evidence of Real Relief (/en/evidence-of-relief.html)

## Your solution should be unique, too

Where many one-size-fits-all treatments fail to provide long-term relief, Boston Scientific therapies can be customized to treat your unique pain. The more we can personalize your treatment, the more likely you are to experience lasting pain relief.

Spinal Cord Stimulation (SCS) [\(/en/chronic-pain-solutions/spinal-cord-stimulation.html\)](/en/chronic-pain-solutions/spinal-cord-stimulation.html)



SCS therapy uses an implanted device to deliver mild electrical impulses that **interrupt pain signals** your nerves send through your spinal cord. This can help **prevent you from perceiving the pain.**

Vertiflex™ Procedure+ [\(/en/chronic-pain-solutions/vertiflex-procedure.html\)](/en/chronic-pain-solutions/vertiflex-procedure.html)



This minimally invasive outpatient procedure uses a small spacer to **relieve pain associated with lumbar spinal stenosis (LSS).**

Radiofrequency Ablation (RFA) [\(/en/chronic-pain-solutions/radiofrequency-ablation.html\)](/en/chronic-pain-solutions/radiofrequency-ablation.html)



RFA is a minimally invasive outpatient procedure that uses thermal energy to **interrupt pain signals at the source.**

[Explore Solutions for Your Relief \(/en/evidence-of-relief.html\)](/en/evidence-of-relief.html)

Real stories, real results [\(https://www.bostonscientific.com/\)](https://www.bostonscientific.com/)

Find a Pain Doctor (/en/personal-support-resources/tools-you-can-use/find-a-pain-doctor.html) Learn more from the patients who use these technologies and see how well they work.

About Pain.com (/en/about.html)

Search

(/en/search.html)

Pain.com (/en.html) Understand Your Pain (/en/understand-your-pain.html) (/en/personal-support-resources/tools-you-can-use/personal-pain-relief-evaluation.html) (/en/evidence-of-relief/clinical-trials.html) (/en/evidence-of-relief/clinical-trials.html)

Explore Solutions for Your Relief (/en/chronic-pain-solutions.html)

See Evidence of Real Relief (/en/evidence-of-relief.html)

Get Personal Support and Resources (/en/personal-support-resources.html)

"I am extremely grateful for what this system has done for me."

- Neil D. (left), SCS patient since 2011

### Connect With a Patient Ambassador

Talk one-on-one with a real patient who has volunteered to share their experience finding lasting pain relief with a Boston Scientific solution.

Contact an Ambassador (/en/evidence-of-relief/talk-to-a-patient-ambassador.html)

## Welcome to your relief library

We've gathered resources on drug-free pain management. Find pertinent information and answers here. Or reach out to us directly.

(/en/personal-support-resources/tools-you-can-use.html)

Tools You Can Use (/en/personal-support-resources/tools-you-can-use.html)

(/en/personal-support-resources/live-educational-webinars.html)

Live Webinars (/en/personal-support-resources/live-educational-webinars.html)

(/en/personal-support-resources/questions-and-answers.html)

Questions & Answers (/en/personal-support-resources/questions-and-answers.html)

(/en/personal-support-resources/guides-and-brochures.html)

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(/en/personal-support-resources/educational-videos.html)

Educational Videos (/en/personal-support-resources/educational-videos.html)

(/en/personal-support-resources/connect-with-us.html)

Connect With Us (/en/personal-support-resources/connect-with-us.html)

# Let's find your relief

(https://www.bostonscientific.com/)

Wondering if these solutions may be right for you? Take this quick quiz and find out.

Question 1 / 8

[Find a Pain Doctor \(/en/personal-support-resources/tools-you-can-use/find-a-pain-doctor.html\)](/en/personal-support-resources/tools-you-can-use/find-a-pain-doctor.html)

Have you been suffering from pain for more than 6 months?

Get started. →

[About Pain.com \(/en/about.html\)](/en/about.html)

Search

YES

[\(/en/search.html\)](/en/search.html)

NO

[Pain.com \(/en.html\) Understand Your Pain \(/en/understand-your-pain.html\) Find Your Relief \(/en/personal-support-resources/tools-you-can-use/personal-pain-relief-evaluation.html\)](/en/personal-support-resources/tools-you-can-use/personal-pain-relief-evaluation.html)

Explore Solutions for Your Relief (/en/chronic-pain-solutions.html)

†Superion™ Indirect Decompression System.

See Evidence of Real Relief (/en/evidence-of-relief.html)

Get Personal Support and Resources (/en/personal-support-resources.html)

(https://www.bostonscientific.com/)

[Find a Pain Doctor \(/en/personal-support-resources/tools-you-can-use/find-a-pain-doctor.html\)](/en/personal-support-resources/tools-you-can-use/find-a-pain-doctor.html)

[About Pain.com \(/en/about.html\)](/en/about.html)

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[Pain.com \[Find Your Relief \\(/en/personal-support-resources/tools-you-can-use/personal-pain-relief-evaluation.html\\)\]\(/en/personal-support-resources/tools-you-can-use/personal-pain-relief-evaluation.html\)](/en/personal-support-resources/tools-you-can-use/personal-pain-relief-evaluation.html)

[Explore Solutions for Your Relief \(/en/chronic-pain-solutions.html\)](/en/chronic-pain-solutions.html)

[See Evidence of Real Relief \(/en/evidence-of-relief.html\)](/en/evidence-of-relief.html)

[Get Personal Support and Resources \(/en/personal-support-resources.html\)](/en/personal-support-resources.html)



**Find a Pain Doctor (/en/personal-support-resources/tools-you-can-use/find-a-pain-doctor.html)**

866.360.4747 (tel:866.360.4747)

Available 5 AM to 5 PM PT, Monday through Friday

**About Pain.com (/en/about.html)**

Get email updates (/en/personal-support-resources/connect-with-us.html)

Join our (https://www.youtube.com/bscineuro) YouTube channel

**Understand Your Pain (/en/understand-your-pain.html)**

**Search**  
Learn About Treating Pain (/en/understand-your-pain/about-treating-pain.html)

**Explore Solutions for Your Relief (/en/chronic-pain-solutions.html)**

Spinal Cord Stimulation (SCS) (/en/chronic-pain-solutions/spinal-cord-stimulation.html)

**See Evidence of Real Relief (/en/evidence-of-relief.html)**

Real Success Stories (/en/evidence-of-relief/success-stories.html)

Proven Clinical Results (/en/evidence-of-relief/clinical-results.html)

Talk To A Patient Ambassador (/en/evidence-of-relief/talk-to-a-patient-ambassador.html)



**Find Your Relief (/en/personal-support-resources/tools-you-can-use/personal-pain-relief-evaluation.html)**

**Understand Your Pain (/en/understand-your-pain.html)**

**Explore Solutions for Your Relief (/en/chronic-pain-solutions.html)**

**Help Manage Your Pain (/en/understand-your-pain/help-manage-your-pain.html)**

**See Evidence of Real Relief (/en/evidence-of-relief.html)**

**Get Personal Support and Resources (/en/personal-support-resources.html)**

**Learn About Pain Doctors (/en/understand-your-pain/about-doctors.html)**

**Why Choose Boston Scientific? (/en/chronic-pain-solutions/why-choose-boston-scientific.html)**

**Care for Someone With Pain (/en/understand-your-pain/care-for-someone-with-pain.html)**

**Get Personal Support and Resources (/en/personal-support-resources.html)**

**Learn About Treating Pain (/en/personal-support-resources/tools-you-can-use.html)**

**Live Educational Webinars (/en/personal-support-resources/live-educational-webinars.html)**

**Questions & Answers (/en/personal-support-resources/questions-and-answers.html)**

**Guides & Brochures (/en/personal-support-resources/guides-and-brochures.html)**

**Educational Videos (/en/personal-support-resources/educational-videos.html)**

**Connect With Us (/en/personal-support-resources/connect-with-us.html)**

**Vertiflex Procedure (/en/chronic-pain-solutions/vertiflex-procedure.html)**

**Radiofrequency Ablation (/en/chronic-pain-solutions/radiofrequency-ablation.html)**

**Why Choose Boston Scientific? (/en/chronic-pain-solutions/why-choose-boston-scientific.html)**

**About Pain.com (/en/about.html)**

## For Healthcare Providers

Deliver effective, personalized relief solutions for your patients with back, neck, shoulder, leg, or lower limb pain

**See Our Solutions (https://www.bostonscientific.com/en-US/medical-specialties/pain-medicine.html)**

Boston Scientific is dedicated to transforming lives through innovative medical solutions that improve the health of patients around the world.

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**Find Your Pain Doctor** **Get Personal Support Resources/Tools You Can Use/Personal Pain Relief Evaluation**  
(https://www.bostonscientific.com/86704/AC)

**About Pain.com (/en/about.html)**

**Search**

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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, are poor surgical risks, or are pregnant.

Boston Scientific's ImageReady™ MRI Technology makes safe MRI head scans possible. Patients implanted with the Precision Spectra™ or Spectra WaveWriter™ Spinal Cord Stimulator Systems with ImageReady™ MRI Technology are MR Conditional™ only when exposed to the MRI environment under the specific conditions defined in the applicable ImageReady™ MRI Head Only Guidelines for Precision Spectra™ or Spectra WaveWriter™ Spinal Cord Stimulator Systems.

Boston Scientific's ImageReady™ MRI Full Body Technology makes safe MRI scans possible. The Precision Montage™ MRI, WaveWriter Alpha™ and WaveWriter Alpha™ Prime SCS Systems with ImageReady™ MRI Full Body Technology are MR Conditional™ only when exposed to the MRI environment under the specific conditions defined in the applicable ImageReady™ MRI Full Body Guidelines for Precision Montage™ MRI or WaveWriter Alpha™ and WaveWriter Alpha™ Prime Spinal Cord Stimulator Systems.

Warnings. Patients implanted with Boston Scientific Spinal Cord Stimulator Systems without ImageReady™ MRI Technology should not be exposed to Magnetic Resonance Imaging (MRI). Exposure to MRI may result in a loss of pain relief, 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 using therapy that generates paresthesia should not operate motorized vehicles such as automobiles or potentially dangerous machinery and equipment with the stimulation on. Stimulation must be turned off first in such cases. For therapy that does not generate paresthesia (i.e. subperception therapy) it is less likely that sudden stimulation changes resulting in distraction could occur while having stimulation on when operating moving vehicles, machinery, and equipment. Your doctor may be able to provide additional information on the Boston Scientific Spinal Cord Stimulator systems. For complete indications for use, contraindications, warnings, precautions, and side effects, call 866.360.4747 or visit Pain.com.

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

Indications for Use. The Superior™ Indirect Decompression System (IDS) is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, having radiographic evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. The Superior™ Interspinous Spacer is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, with or without back pain, who have undergone at least 6 months of non-operative treatment. The Superior Interspinous Spacer may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated at no more than two levels, from L1 to L5.

Contraindications, warnings, precautions, side effects. The Superior Indirect Decompression System (IDS) is contraindicated for patients who: have spinal anatomy that prevent implantation of the device or cause the device to be unstable in situ (i.e., degenerative spondylolisthesis greater than grade 1), Cauda equina syndrome, or prior decompression or fusion at the index level, scoliosis or spinous process fractures, osteoporosis, infection, allergy or reaction to any metal or implant or a high Body Mass Index. Avoid strenuous activity for 6 weeks after surgery, contact your physician if there is fluid leaking from your incision, if you have pain, swelling or numbness in your legs or buttocks or if you fall. Refer to the Instructions for Use provided on www.vertiflex.com for additional Indications for Use, contraindications information and potential adverse effects, warnings, and precautions prior to using this product.

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Indications for Use. The Boston Scientific Radiofrequency Generators, associated Radiofrequency Lesion Probes and RF Cannula are indicated for use in procedures to create radiofrequency lesions for the treatment of pain or for lesioning nerve tissue for functional neurosurgical procedures. The Boston Scientific RF Injection Electrodes are used for percutaneous nerve blocks with local anesthetic solution for radiofrequency lesioning of peripheral nerve tissue only. The Boston Scientific LCED and Stereotactic TCD Electrodes are indicated for use in radiofrequency (RF) heat lesioning of nervous tissue including the Central Nervous System.

Warnings. For a patient with a cardiac pacemaker, contact the pacemaker company to determine whether the pacemaker needs to be converted to fixed rate pacing during the radiofrequency procedure. Refer to the Instructions for Use provided with Boston Scientific generators, electrodes and cannulas for potential adverse effects, additional warnings and precautions prior to using these products.

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