



Boston
Scientific

Turning your back on chronic pain

WAVEWRITER
ALPHA™

Spinal Cord Stimulator System



A few painful truths



Estimates show that approximately 25%–35% of adults in European countries experience chronic pain.¹

In fact, chronic pain reduces people's quality of life more than almost any other condition.² The journey to pinpointing and easing the source of the pain can be a long and difficult one.

The European Painful Truth Survey found that:

- On average people live with chronic pain for up to 7 years,³ and over a fifth of people with chronic pain will endure the pain for 20 years or more.⁴
- A third of people with chronic pain are in constant pain,³ and 68% of respondents are still in pain for more than 12 hours a day despite treatment.⁵ Conventional treatments include physical therapy, drug therapy or surgery.
- Only 36% are satisfied with pharmacological treatment⁵ such as non-steroidal anti-inflammatory drugs (NSAIDs), anti-neuropathic agents and opioids.

If your chronic pain denies you daily tasks and pleasures, and takes a toll on you emotionally, it can have a significant impact on your quality of life. Whilst Spinal Cord Stimulation (SCS) does not cure chronic pain it can provide effective and long lasting relief in addition to medications or other treatments.



Understanding Spinal Cord Stimulation

Take control of your pain

If you're reading this brochure, your doctor believes Spinal Cord Stimulation may be an option for you. Read more to find out how SCS could help you return to some of the activities that chronic pain has made difficult – or even to discover **new passions you never knew you could have.**

- 80% of SCS patients report that their **pain has either been completely controlled or at least halved** 12 months after receiving their SCS implant.³
- Turning to SCS from the onset of chronic pain symptoms could lead to **improved health outcomes** for you.⁶
- SCS could also be a **more effective alternative to repeat operations or increased opioid use.**⁷



How could Spinal Cord Stimulation help me?

SCS could provide you with an **alternative to medication or surgery** and may help you experience adequate pain relief.

Most importantly, it could support you in **taking back control over your life** and enjoying some of life's pleasures that were difficult to enjoy before.

SCS: Opening up new possibilities

- SCS can treat pain **in more than one area**, such as both your upper and lower back, or both your neck and shoulder.
- SCS can be taken **together with other pain medications.**
- SCS is designed for **maximum control and freedom**: you set the frequency and duration of stimulation.
- SCS **can be trialed** for a few weeks prior to the full implant – so you can discover if this therapy option works well for you.

How does spinal cord stimulation work?

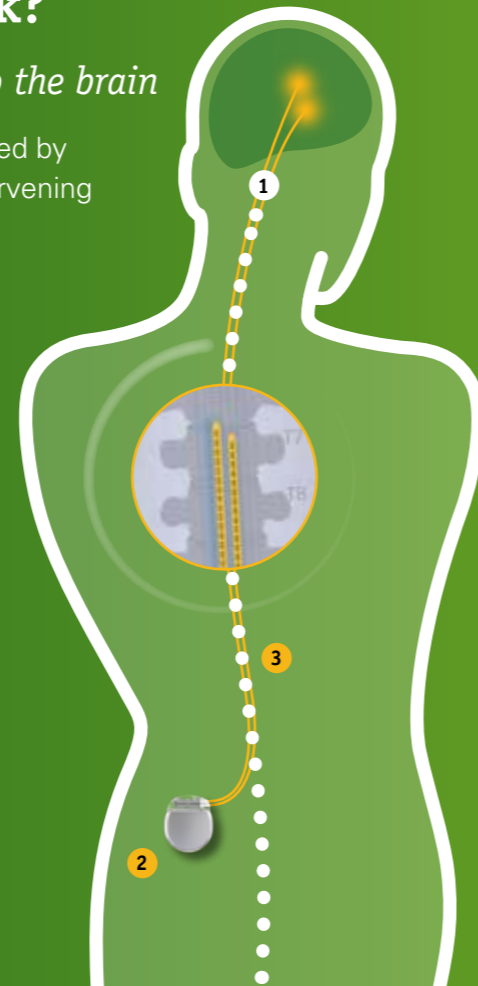
Pain travels along nerve fibers through the spinal cord to the brain

SCS therapy starts with this simple, basic premise: Since pain is carried by electrical nerve impulses **along the spinal cord to the brain ①**, intervening in the nervous system's impulse flow is key to managing pain.

A small **pulse generator ②** and **insulated wires ③** are implanted into the body, near the spinal column. Directed by an external remote control, electrical impulses from the pulse generator interrupt pain signals as they travel to the brain.

With older SCS models, patients experienced these electrical impulses as a gentle, tingling feeling called parasthesia. Thanks to the latest SCS technology from Boston Scientific, you have more choice over how you experience these electrical impulses. With some settings, patients can experience a gentle tingling sensation known as parasthesia. With other settings patients will simply feel pain relief without any additional sensations.

The choice is in your hands.



The intended result is a soothing, smoothing sensation.

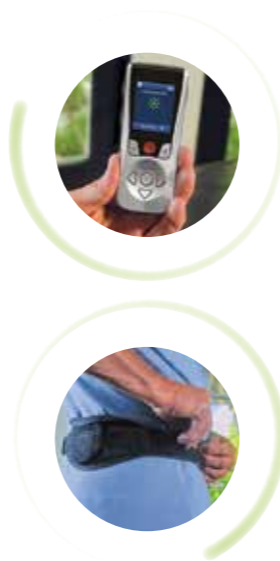
Pain signals are interrupted while the therapy is active and there is no need for major surgery.



What is the WaveWriter™ Alpha System?

WaveWriter™ Alpha SCS System: Making life smoother

- The SCS implant can be positioned at the ideal depth to locate the source of your pain, so your therapy can be **best targeted and tailored for you**.
- The basic components of your WaveWriter™ Alpha System are: the **SCS device** itself and a **wireless remote control**, as well as a **charging belt**. The system was designed for your **maximum mobility and freedom** to fit SCS into your lifestyle.



The WaveWriter™ Alpha Spinal Cord Stimulator System:



The **WaveWriter™ Alpha Spinal Cord Stimulator System** offers extended coverage of the spinal cord and covers both simple unilateral pain and more complex bilateral pain – all with a small, comfortable implant.

The **WaveWriter™ Alpha SCS System** is available as rechargeable option or a non-rechargeable option. Please ask your health care professional to discuss which option might be the best for your needs.



Want to give your SCS system a test drive?

Taking the decision to have an SCS implant may be an important step on your journey to fighting chronic pain. That's why we offer you a **specially designed SCS Trial System** so you can see for yourself if SCS could be for you.

With the SCS Trial System, you have the chance to test out stimulation with your own **cordless remote**, record your experiences in a special **SCS Notebook** and most importantly see what stimulation really feels like for you and to what extent your chronic pain is relieved.

Recording your experiences will help you and your doctor decide whether your trial SCS experience has been a success for you. Every individual is different but the key success criteria are a minimal 50% reduction in pain and a reduced need for medication, as well as being able to return to some daily activities you weren't able to do before.



Meet Sabrina and read how SCS turned her life around

"I'm really happy because I have gone back to doing what I could not do before. Now I leave for work without a care in the world. I come home, I tidy everything up, I put everything in order, I go out, I go to the gym until the evening. I don't stop for a second and this is thanks to my neurostimulator."

Sabrina Bassi
Chronic Pain Patient



After a car accident in 2004, Sabrina was diagnosed with incomplete paraplegia. After several years, the burning sensations in her legs became worse and worse, until her medication could no longer keep the pain under control. However, finding out that she was a candidate for SCS gave Sabrina **a new lease of life** – and a taste for a new challenge.

After having long dreamed of trying out water skiing, she finally took to the water and began participating in competitions. Soon after receiving her SCS implant, Sabrina travelled to international competitions in Norway and won a silver medal in the sport she had become so passionate about.

* Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.



Sabrina's SCS implant gives her the comfort to enjoy daily life with her boyfriend and the confidence to pursue new goals.

*Her next challenge is the world championships in Australia.**

10 things

... you need to know about
Spinal Cord Stimulation



1. What is SCS?

After several decades of use, SCS treatment has been shown to be a safe and effective treatment,⁸ with over 350,000 people successfully treated worldwide.⁹

The SCS procedure should be carried out by an experienced specialist physician working as part of an interdisciplinary team.

As with any surgical procedure, there are risks involved and potential side effects vary from patient to patient. However, these are often temporary and stimulation can be adjusted to reduce or reverse these. You should discuss potential risks and side effects with your physician.

2. What does the SCS Trial System involve?

With the SCS Trial System, you can experience what SCS feels like for you before deciding with your physician if this could be an option for you. You should receive a special SCS Notebook to record your experiences and this comes with a helpful pain diagram.

After a recommendation from your physician, you will have a procedure (usually lasting 1 to 2 hours) to have a temporary implant inserted. The test drive with the temporary system then lasts on average between 3 days and 3 weeks. If the therapy proves to be the right one for you, a full implant will follow. Otherwise, the trial implant can be removed.

During the test period, you should be careful to avoid too many activities that could risk pulling the external leads out of place. You should also stick to sponge baths so as to keep the system dry.

3. Will I be pain-free after SCS? What about my pain medication?

Every patient is an individual. This means that the amount of pain relief experienced differs depending on the person. The SCS Trial Procedure helps you decide if the level of pain reduction from SCS is right for you. A pain reduction of at least 50% is considered a standard benchmark. The same is true for medication. While some patients find they no longer need pain medication, others may simply reduce their medication. You should always ask your doctor before making any changes to your dosage.

4. How long will my SCS system last?

The rechargeable WaveWriter™ Alpha SCS System last a minimum of 12 years.

5. How quickly can I recover after surgery?

Patients are advised to avoid any strenuous activity like heavy lifting for the first few weeks. It can take several weeks for you to return to normal activities and you may also feel some initial pain or discomfort at the incision sites. Your physician can give you detailed information about managing your medication and daily activities during this time. SCS treatment is designed to help you lead a healthy and active lifestyle and potentially even manage activities that weren't possible before, as far as your unique condition and treatment success allows.

6. Can I actually control the stimulation therapy?

SCS is designed precisely to help you regain control of your pain so as to lead a better quality of life.

Thanks to a cordless remote control and program settings designed specifically for you, you can:

- Turn your stimulation on and off
- Increase or decrease the level of stimulation
- Target different individual areas of pain at the same time, each with a different amount of stimulation
- Give a rating of the therapy

7. Do I need to use my SCS system 24 hours a day?

Boston Scientific's SCS systems are designed for 24 hour use, leaving you the option to decide when and how much you turn your stimulation on. There are a few limitations you should bear in mind and discuss with your physician though. For example, you should not charge your SCS system while sleeping or use the system at the same time as driving.

8. How can I charge my SCS device?

Thanks to a lightweight cordless charger that fits into a waistbelt, recharging your SCS device is designed to be as simple and convenient as possible. The charger itself can easily be recharged through a base station plugged into a power socket. For more information, read your SCS Quick Start Guide Charging System booklet.

Your wireless remote will remind you when your implant battery is low and needs charging. However if the battery runs down, the system is designed to prevent any permanent damage, allowing the battery to function normally again once charged.

9. Is it possible to have an MRI with an SCS implant?

You may be eligible for an MRI scan depending on the SCS system you have received. Take a look at the Patient Trial

Handbook to find out more about what other diagnostic and medical procedures are possible with an SCS implant.

10. Will other people be able to notice my SCS device?

All Boston Scientific SCS systems are designed for maximum comfort. Your doctor can also position the device in the most comfortable and convenient location for you. Since the SCS stimulator and the wires are placed under the skin, they are often hardly noticeable from the outside.



SCS is designed to bring back your passion for life

By reducing your chronic pain, SCS aims to help you return to some of the **activities you most enjoy in life**, or even take up new ones.*

Here are just some of the things individuals may be able to do after SCS surgery:

Socializing with friends and family

Gardening

Swimming

Yoga

Riding your bicycle

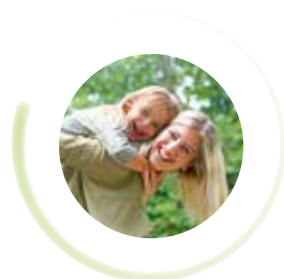
Hiking

Playing with your children

Sailing



Think about **taking up a new or hold hobby** – or becoming an international water skiing champion.



Talk through what's right for you

SCS is designed to help you potentially return to doing some of your favorite things in life.

However, make sure to always **talk to your doctor** about what activities are right for you, as well as any precautions you should take with your SCS device.

Where can I go to learn more?

For more information, go to
<http://www.bostonscientific.com/en-EU/home.html>



References

- ¹ Breivik H et al. The individual and societal burden of chronic pain in Europe: the case for strategic prioritisation and action to improve knowledge and availability of appropriate care. *BMC Public Health* 2013; 13: 1229.
- ² Department of Health. Annual report of the Chief Medical Officer; Pain, breaking through the barrier. 2008. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/AnnualReports/DH_096206 Accessed December 2012
- ³ British Pain Society. Pain in Europe – A Report <http://www.britishpainsociety.org/Pain%20in%20Europ%20survey%20report.pdf> Accessed December 2012.
- ⁴ Breivik H et al. Survey of chronic pain in Europe: prevalence, impact on daily life, and treatment. *Eur J Pain* 2006;10:287–333.
- ⁵ Painful Truth Survey, IML Research – sponsored by Boston Scientific, 2012.
- ⁶ Krames ES. et al. Using SAFE principals when evaluating electrical stimulation therapies for the pain of Failed Back Surgery Syndrome. *Neuromodulation* 2011; 14: 299–311.
- ⁷ NICE. NICE technology appraisal guidance 159 Pain (chronic neuropathic or ischaemic) – spinal cord stimulation (TA159). October 2008.
- ⁸ Kumar K, Taylor RS, Jacques L, Eldabe S, Meglio M, Molet J, Thomson S, O’Callaghan J, Eisenberg E, Milbouw G, Buchser E, Fortini G, Richardson J, North RB. 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 Oct;63(4):762–70.
- ⁹ Data on file.



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