# Boston Scientific Launches Spectra WaveWriter™ Spinal Cord Stimulator System in Europe

**System offers multiple non-drug therapies for people with chronic pain**

Boston today announced the launch of the Spectra WaveWriter™ Spinal Cord Stimulator (SCS) System in Europe. The Spectra WaveWriter SCS System is the first and only system for the treatment of chronic pain to be able to simultaneously combine paresthesia-based and sub-perception therapy.

The new system with these therapeutic options is designed to allow physicians and patients to customise therapy and capture real-time feedback to treat chronic and debilitating pain successfully. SCS works by sending electrical impulses to the spinal cord and masking the pain messages traveling to the brain.

These electrical impulses can vary in frequency, pulse width and amplitude and provide pain relief with a light tingling sensation known as paresthesia-based therapy or with sub-perception therapy that works without sensation.

The Spectra WaveWriter SCS System allows physicians and patients to specifically target one area of pain, or multiple areas, with one or both types of therapy to address individual needs. Patients are also able to provide real-time feedback, using the Spectra WaveWriter SCS System Remote Control which is designed to simplify and personalise their therapy.

“Pain is very personal, and everyone experiences it differently. Pain also changes over time, which for chronic pain patients means that their bodies may become accustomed to treatment and its effectiveness declines,” said Dr Vivek Mehta, Consultant in Pain Medicine and Honorary Senior Lecturer, Queen Mary University, London and Director, Pain & Anaesthesia Research Centre, Barts Health, London.

“The Spectra WaveWriter SCS System allows us to combine multiple treatment options in one single device, intended to give patients truly personalised therapy that evolves just as their pain does to provide lasting relief.”

The Spectra WaveWriter SCS System was developed with more than a decade of clinical research focused on optimising sub-perception and delivering multiple therapies intended for more effective, long-term pain relief. These studies include the WHISPER study and the PROCO study*.

In addition, the first clinical multi-centre, observational real-world data with over 200 patients using the Spectra WaveWriter SCS System demonstrated significant improvement in overall pain, with almost 90 percent of patients reporting more than a 50 percent improvement in their pain[1].

“We understand the complex challenges people living with chronic pain face daily. Often these people have lived with agonising and unbearable pain for years, having tried numerous treatments that simply do not work,” said Vincent Sourdaine, vice president, Neuromodulation, Boston Scientific EMEA.

“We are committed to research and development of treatment options for the millions of people who are severely affected by chronic pain and are very pleased to be introducing this new system to help patients manage this.”

Chronic pain is a widespread problem with 1 in 5 adults in Europe – or 100 million people – affected[2]. SCS is a non-opioid alternative for treating pain; the use of medications such as opioids has increased sharply in recent years in Europe[3], with around 1.3 million high-risk users of opioid drugs according to a recent report[4].

About Boston Scientific

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 35 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.eu and connect on Twitter and Facebook.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like “anticipate,” “expect,” “project,” “believe,” “plan,” “estimate,” “intend” and similar words.

These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding our product launches and product performance and impact.

If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements.

These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; the closing and integration of acquisitions; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control.

For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – Risk Factors in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – Risk Factors in Quarterly Reports on Form 10-Q we have filed or will file hereafter.

We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

***The PROCO study was a multi-centre, prospective, double-blind, randomized study in which patients acted as their own control.**

**This study established in de novo patients that similar pain relief and improvement in quality of life measures are achieved independent of the type of frequency (from 1 kHz up to 10 kHz) used in sub-perception SCS therapy when the proper target and dose are identified.**

**The WHISPER study is a multi-centre, prospective, cross-over, randomized, and controlled study which evaluated the long-term safety and effectiveness of sub-perception SCS pain relief therapy.**

**1 Outcomes Using an SCS Device Capable of Delivering Combination Therapy (Simultaneous or Sequential) and Advanced Waveforms/Field Shapes. Metzger C et al. Poster EU-INS 2018**

**2 Societal Impact of Pain, 2016. Abstract & Background Booklet. https://www.sip-platform.eu/sip2016booklet. Last accessed: January 2019**

**3 Trends in the consumption of opioids for the treatment of severe pain in Europe, 1990-2016. Bosetti et al. https://www.ncbi.nlm.nih.gov/pubmed/30407692 Last accessed: January 2019.**

**4 European Drug Report, Trends and Developments. European Monitoring Centre for Drugs and Drug Addiction. Last accessed: January 2019 www.emcdda.europa.eu/system/files/publications/4541/TDAT17001ENN.pdf**

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