

## **Boston Scientific Announces CE Mark Approval of the Vercise™ Neural Navigator 3 Programming Software**

Boston Scientific Corporation announced the CE Mark approval of the Vercise™ Neural Navigator 3 directional Deep Brain Stimulation (DBS) programming software - the first system that integrates patient-specific 3D brain anatomy and stimulation field modeling into the clinician's programming interface. When used in conjunction with the Vercise Directional DBS System, this innovation is intended to empower physicians to accurately and efficiently optimize personalized DBS therapies for their patients.

The Vercise Directional System, with the Vercise Cartesia™ Directional Lead, is designed to treat the symptoms of Parkinson's Disease (PD), Essential Tremor, and Primary and Secondary Dystonia by delivering precisely targeted electrical stimulation in the brain to provide optimal symptom relief and better control of unwanted side effects. An estimated ten million people worldwide are affected by Parkinson's disease, causing symptoms such as shaking or tremors, muscle stiffness, and slowness of movement.<sup>1</sup> Dystonia is a neurological movement disorder that affects more than half a million men, women, and children across Europe.<sup>2</sup>

"DBS programming can be time intensive as a clinician works through trial and error to identify the right stimulation settings," said Prof. Dr. Jens Volkmann, director and chairman of the Department of Neurology at the University Hospital of Würzburg, Germany. "We now have the ability--with STIMVIEW™ XT--to visualize lead placement in the patient to see how stimulation settings work in real time. This empowers clinicians to optimize therapy in a more efficient manner."

The Vercise Neural Navigator 3 programming software features STIMVIEW XT, which is the most advanced, visualization capability built for DBS programming. A study found that overall programming time with the first-generation GUIDE System was significantly shorter than traditional programming time (n=10, p<0.0001)<sup>3</sup>. Shorter programming time is beneficial as it reduces prolonged periods of time used for adjusting the stimulation settings, which can be stressful and tiring for the patient.

Since receiving CE Mark for the Vercise DBS System in 2012, Boston Scientific has introduced a steady pace of innovation in the field of DBS, including the launch of the Vercise Gevia™ DBS System in 2017, which features the Vercise Cartesia Directional Lead. The Vercise Gevia DBS System provides patients with an unparalleled 25-year battery life.

"Boston Scientific continues to advance Directional DBS with a strong cadence of meaningful innovation," said Maulik Nanavaty, senior vice president and president, Neuromodulation, Boston Scientific. "Vercise Neural Navigator 3 with STIMVIEW XT Technology is an example of how Boston Scientific translates technical complexity into an elegantly simple interface to empower clinicians to improve the lives of patients."

The Vercise Deep Brain Stimulation (DBS) Systems are indicated for use in unilateral or bilateral stimulation of the subthalamic nucleus (STN) or internal globus pallidus (GPi) for treatment of levodopa-responsive Parkinson's disease which is not adequately controlled with medication and for treatment of intractable primary and secondary Dystonia, for persons 7 years of age and older. Thalamic stimulation using the Boston Scientific Vercise DBS System is indicated for the suppression of tremor not adequately controlled by medications in patients diagnosed with Essential Tremor or Parkinson's disease.

### **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 40 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.com](http://www.bostonscientific.com) and connect on [Twitter](#) and [Facebook](#).

1 <http://parkinson.org/Understanding-Parkinsons/Causes-and-Statistics/Statistics>

2 <https://dystonia-europe.org/about-dystonia/dystonia/>

3 Pavese et al., Traditional trial-and-error versus neuroanatomical-3D-image software-assisted deep brain stimulation programming in patients with Parkinson's disease, World Neurosurgery (2019)

### **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.

1. Pavese et al. Traditional trial-and-error versus neuroanatomical-3D-image software-assisted deep brain stimulation programming in patients with Parkinson's disease, 2017 WSSFN Conference, Berlin. 2. 1.5 Tesla MRI conditional when all conditions of use are met. \* The Vercise™ Gevia™ DBS System is not available for use or sale in the U.S. \*\* Vercise Cartesia™ Directional Lead and GUIDE XT - Caution: Investigational Device. Limited by Federal (or U.S.) law to investigational use only. Not available for sale in the U.S.

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