Boston Scientific Receives CE Mark For The Vercise™ Deep Brain Stimulation (DBS) System For Treating Patients With Tremor [EN]

Vercise DBS System is the First DBS System Offering Precise Neural Targeting and a 25-Year Battery Life

Boston Scientific Corporation (NYSE: BSX) has received CE Mark for the Vercise™ Deep Brain Stimulation (DBS) System for the treatment of tremor, including the most common form of this movement disorder known as essential tremor (ET). Tremor is characterized by involuntary and rhythmic shaking, usually associated with difficulty in an activity such as writing or holding and controlling items.

Experts say ET may be as much as 20 times more prevalent than Parkinson's disease.[1] The Vercise DBS System is the first system designed to offer precise neural targeting, allowing physicians to customize therapy for patients with ET. It also features a rechargeable battery that can last up to 25 years.

One of the first commercial implantations of the Vercise DBS System for ET was performed at the University Hospital Cologne, Germany, by a team of physicians, led by Prof. Dr. Veerle Visser Vandewalle, Head of the Department of Stereotaxy and Functional Neurosurgery, and Prof. Dr.Lars Timmermann, neurologist and professor of Neurological Movement Disorders.

"Essential tremor can be very debilitating for patients in their day-to-day activities such as writing and eating," said Prof. Dr. Vandewalle. "The Vercise DBS System provides advanced tremor care through precise neural targeting that is designed to manage ET symptoms effectively and improve patient quality of life."

"The Vercise DBS system features multiple independent current control, which gives clinicians the ability to control stimulation precisely for a neural target to help minimize unwanted side effects," said Prof. Dr. Timmermann. "The 25 year battery life may also help reduce the frequency of surgical interventions to replace depleted batteries."

ET can be a progressive disorder, typically starting on one side of the body, and then gradually affecting both sides. It is most commonly seen in older adults, however the onset of symptoms may occur at any age.2 The exact cause for ET is unknown, but it is found to be mostly hereditary, where children of a parent who has ET have a 50 percent chance of inheriting the condition.[2]

"With the launch of the Vercise DBS System for the treatment of patients with Parkinson's disease in 2012, for dystonia in 2013, and now for tremor, Boston Scientific continues to demonstrate its commitment to provide more access to DBS therapy to more patients," said Maulik Nanavaty, president, Neuromodulation, Boston Scientific. "We believe this advanced technology can play a critical role in improving the lives of patients who suffer from these devastating conditions."

Boston Scientific is an innovation leader in implantable DBS technology. The Vercise DBS System has both CE Mark and TGA (Australia Therapeutic Goods Administration) approval for the treatment of Parkinson's disease. It also has CE Mark for intractable primary and secondary dystonia, and is available for sale in Europe, Israel, Australia and select countries in Latin America.

In the U.S., the Vercise DBS System is investigational and not available for use or sale. The INTREPID clinical trial began enrollment in the U.S. in mid-2013 to evaluate the safety and effectiveness of the Vercise DBS System for the treatment of Parkinson's disease. For more information about the INTREPID clinical trial, click here.

- https://www.ncbi.nlm.nih.gov/pubmed/9452318
- https://essentialtremor.org/wp-content/uploads/2013/06/patienthandbook02142013-final1.pdf

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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 business plans, product launches, markets for our products, clinical trials and data impact, product performance and impact, and competitive offerings. 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; 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 European Parkinson's Disease Association 2013. https://www.epda.eu.com/en/about-the-epda/ Date accessed 4 December 2013.

2 Parkinson's Disease Foundation 2012. https://www.pdf.org/en/parkinson_statistics Date accessed 12 November 2013.

3 European Parkinson's Disease Association 2013. https://www.epda.eu.com/en/about-the-epda/ Date accessed 4 December 2013.

4 Dystonia Europe. Dystonia. https://dystonia-europe.org/about-dystonia/dystonia/ Date accessed 14 November 2013.

5 Epidemiology study of dystonia in Europe (ESDE) Collaborative Group. A prevalence study of primary dystonia in eight European countries. J. Neurology. 2000. 247:787-792.

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