Boston Scientific launches GUIDE[™] XT System for Visualization of Deep Brain Stimulation

Boston Scientific Corporation today announced the launch of the GUIDE[™] XT System for visualization of Deep Brain Stimulation (DBS) in Europe. The GUIDE XT System is the first DBS visualization system built for directionality that utilizes patient specific anatomy and stimulation field modeling. This technology provides physicians with 3-D image planning capability and when used in conjunction with the Vercise[™] DBS Systems, enables physicians to personalize and optimize DBS treatment.

DBS treats movement disorder symptoms in patients with Parkinson's Disease, dystonia or essential tremor. The procedure stimulates a targeted region of the brain through implanted leads that are powered by a device called an implantable pulse generator (IPG).

The GUIDE XT System automatically detects the location of the leads, implanted by a neurosurgeon, in the imaging of the brain. Following the implant, a clinician programs a patient's device and the GUIDE XT System can be used to help visualize the stimulation field and efficiently determine the most appropriate settings for each patient.

"Current practice for DBS programming can involve multiple visits and hours of 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 Wurzburg, Germany. "Unlike visualization systems that use a generic atlas, the GUIDE XT System enables us to visualize the lead placement in the patient's brain. By simulating and visualizing different stimulation settings, it is much easier to decide upon initial programming which is likely to yield beneficial results in a given patient."

"Direct visualization of pertinent structures within an individual patient's brain is very important in DBS. This is the 'gold standard' when planning the surgical trajectory for lead implantation," explained Professor Ludvic Zrinzo, Head of the UCL Unit of Functional Neurosurgery, Queen Square, London. "GUIDE XT integrates surgical planning with radiological verification of lead placement, promising a smoother workflow and allowing surgeons to better assist their clinical colleagues when they program DBS parameters for each patient."

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). Shorter programming time is beneficial for both physicians and patients as it can eliminate the need for additional appointments and reduce prolonged periods of time adjusting the stimulation settings which can be stressful and tiring.

"The GUIDE XT System is designed to take the complexity out of DBS programming, providing physicians with individualized and supplemental information which could lead to better patient outcomes." said Maulik Nanavaty, senior vice president and president, Neuromodulation, Boston Scientific. "Boston Scientific is dedicated to providing advanced solutions and meaningful innovations to help clinicians improve the lives of patients through personalized therapy."

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 Cartesia[™] Directional Lead** to provide rechargeable, magnetic resonance (MR) conditional system2 with directionality. The company also launched the Vercise DBS System in the United States late last year.

GUIDE XT** was developed in partnership with Brainlab AG, a software-driven medical technology company that helps improve patient treatment planning and surgical navigation. The exclusive collaboration between Brainlab and Boston Scientific provides a comprehensive portfolio covering all key elements of Deep Brain Stimulation (DBS) therapy for patients and physicians.

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 30 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 <u>www.bostonscientific.eu</u> and connect on <u>Twitter</u> and <u>Facebook</u>.Boston Scientific Corporation today announced the launch of the GUIDE[™] XT System for visualization of Deep Brain Stimulation (DBS) in Europe. The GUIDE XT System is the first DBS visualization system built for directionality that utilizes patient specific anatomy and stimulation field modeling. This technology provides physicians with 3-D image planning capability and when used in conjunction with the Vercise[™] DBS Systems, enables physicians to personalize and optimize DBS treatment. DBS treats movement disorder symptoms in patients with Parkinson's Disease, dystonia or essential tremor. The procedure stimulates a targeted region of the brain through implanted leads that are powered by a device called an implantable pulse generator (IPG).

The GUIDE XT System automatically detects the location of the leads, implanted by a neurosurgeon, in the imaging of the brain. Following the implant, a clinician programs a patient's device and the GUIDE XT System can be used to help visualize the stimulation field and efficiently determine the most appropriate settings for each patient.

"Current practice for DBS programming can involve multiple visits and hours of 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 Wurzburg, Germany. "Unlike visualization systems that use a generic atlas, the GUIDE XT System enables us to visualize the lead placement in the patient's brain. By simulating and visualizing different stimulation settings, it is much easier to decide upon initial programming which is likely to yield beneficial results in a given patient."

"Direct visualization of pertinent structures within an individual patient's brain is very important in DBS. This is the 'gold standard' when planning the surgical trajectory for lead implantation," explained Professor Ludvic Zrinzo, Head of the UCL Unit of Functional Neurosurgery, Queen Square, London. "GUIDE XT integrates surgical planning with radiological verification of lead placement, promising a smoother workflow and allowing surgeons to better assist their clinical colleagues when they program DBS parameters for each patient."

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). Shorter programming time is beneficial for both physicians and patients as it can eliminate the need for additional appointments and reduce prolonged periods of time adjusting the stimulation settings which can be stressful and tiring.

"The GUIDE XT System is designed to take the complexity out of DBS programming, providing physicians with individualized and supplemental information which could lead to better patient outcomes." said Maulik Nanavaty, senior vice president and president, Neuromodulation, Boston Scientific. "Boston Scientific is dedicated to providing advanced solutions and meaningful innovations to help clinicians improve the lives of patients through personalized therapy."

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 Cartesia[™] Directional Lead** to provide rechargeable, magnetic resonance (MR) conditional system2 with directionality. The company also launched the Vercise DBS System in the United States late last year.

GUIDE XT** was developed in partnership with Brainlab AG, a software-driven medical technology company that helps improve patient treatment planning and surgical navigation. The exclusive collaboration between Brainlab and Boston Scientific provides a comprehensive portfolio covering all key elements of Deep Brain Stimulation (DBS) therapy for patients and physicians.

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 30 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 <u>www.bostonscientific.eu</u> and connect on <u>Twitter</u> and <u>Facebook</u>.

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.

https://news.bostonscientific.eu/2018-09-26-Boston-Scientific-launches-GUIDE-TM-XT-System-for-Visualizationof-Deep-Brain-Stimulation