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Medtronic device will collect data as it treats brain disorders

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A new deep brain stimulation system by Medtronic can sense and record brain activity at the same time it delivers therapy to treat Parkinson's symptoms, essential tremors and epilepsy. The data collected by the Activa PC+S deep brain stimulation system will be available to researchers working to better understand how to treat neurological and psychological diseases, Medtronic said.

The hope is that the new device, and what doctors learn from it, will eventually lead to development of a "closed loop" system that can automatically adjust its program to meet the changing needs of the patient. Currently, medical staff have to adjust device settings manually.

For now, the device will collect brain signals that researchers can use to study neurological and psychological disorders and how to adapt technology to best treat them, said Lothar Krinke, vice president and general manager of the Deep Brain Stimulation business in Medtronic's Neuromodulation division.

"Where we want to go and what we have already done in animal research is to totally close the loop," he said, adding that automated programming could provide a number of advantages.

For instance, he said, with Parkinson's, the device may need to stimulate part of the brain only occasionally, rather than send a constant electrical pulse. Whereas, with epilepsy, the device could sense the onset of a seizure and time the treatment to head off the episode.

"This is one of the most exciting things that are happening in deep brain stimulation," said Krinke, a former researcher.

Deep brain stimulation, or DBS, therapy uses a surgically implanted medical device, similar to a pacemaker, to deliver mild electrical pulses to targeted areas of the brain to control symptoms of movement disorders and other diseases. The stimulation can be programmed and adjusted to maximize symptom control and minimize side effects. More than 100,000 patients worldwide have received Medtronic's DBS therapy.

The Activa PC+S system is not approved by the U.S. Food and Drug Administration for commercial use in the United States, and will be made available to physicians for investigational use only. It met the European standards of CE Mark approval in January.

The first implant took place in Munich, Germany, in a person with Parkinson's disease. The system uses sensing technology and an adjustable algorithm to gather brain signals at moments selected by a physician. That data will be made available to physicians worldwide for use in clinical studies. They will use the system to map the brain's responses to DBS therapy and explore new applications for that therapy.

The therapy is approved in many locations around the world, including Europe and the United States, for the treatment of symptoms of essential tremor, advanced Parkinson's disease and chronic intractable primary dystonia. In Europe, Canada and Australia, DBS therapy is approved for the treatment of refractory epilepsy. DBS therapy is also approved for the treatment of severe, treatment-resistant obsessive-compulsive disorder in the European Union and Australia, and in the United States under a Humanitarian Device Exemption.

But Krinke said the business potential is even greater.

"The opportunity is huge. Even in our most penetrated market of Parkinson's we have less than 20 percent of the patients who could benefit from DBS," he said. "Less than 5 percent worldwide."

An estimated 1 million people in the U.S. suffer from Parkinson's, he said.

Deep brain stimulation is part of what is called neuromodulation, in which a device is used to deliver targeted and regulated electrical pulses and drugs to specific sites in the nervous system to treat chronic pain or other disease symptoms.

On Tuesday, Medtronic announced the first U.S. implants of its new RestoreSensor SureScan MRI neurostimulation systems - the first and only implantable spinal cord stimulator to treat chronic pain that is FDA approved as safe for MRI scans.

Doctors use MRI scans to detect a wide range of health conditions by viewing highly detailed images of internal organs, blood vessels, muscle, joints, tumors, areas of infection. But the machine's strong magnetic fields and radio frequency pulses can affect spinal cord stimulator systems. This new system is designed to reduce or eliminate the hazards produced by an MRI, Medtronic said.

Developing such MRI-compatible devices is key to providing a wider range of care, said Dr. Mehul J. Desai, director of spine, pain medicine and research at Metro Orthopedics and Sports Therapy in Silver Spring, Md. He is among the first physicians in the U.S. to implant the Medtronic device.

Often, he said, patients suffering from chronic pain have other conditions that make MRI scans necessary.

"It's a huge deal in my opinion," he said. "It directly helps me in the conditions I am treating expand my diagnostic options."