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Medtronic receives CE Mark for the Percept RC rechargeable DBS neurostimulator with BrainSense technology

The next-generation DBS technology is now available in a rechargeable option

Medtronic the world's leading medical technology company today announced it received CE (Conformité Européenne) Mark for its Percept™ RC neurostimulator for deep brain stimulation (DBS). The smallest and thinnest device on the market[1-4], Percept™ RC is the only rechargeable DBS system with BrainSense™ sensing technology[5] to be launched in the European Union (EU).

"This development represents a critical step in our journey to transform Brain Modulation through sensing-enabled DBS," said Amaza Reitmeier, Vice President and General Manager for Medtronic Brain Modulation. "We are excited about the potential of Percept™ RC to provide a comfortable, personalized DBS therapy to those living with Parkinson's Disease, Essential Tremor and Primary Dystonia. Percept™ RC is also the only rechargeable neurostimulator approved to serve patients with Epilepsy."

"In addition to being the smallest DBS device on the market, Percept™ RC combines proprietary battery technology with our brain-sensing technology. These innovations are the culmination of 30 years[6] of investment in clinical trials and R&D to improve the experience of DBS patients," said Domenico De Paolis, Vice President Neuromodulation International, which is part of the Neuroscience Portfolio at Medtronic.

Overdrive™ battery technology provides physicians with flexibility to adjust therapy without impacting battery capacity. With weekly charging, the device has greater than 99% battery capacity at 15 years[7]. What's more, rapid recharging means that patients can charge under normal conditions (from 10% to 90% full) in less than an hour[8].

The Percept™ family of devices also features Medtronic's exclusive BrainSense™ technology, which enables physicians to track patient brain signals and correlate them with patient-recorded events, such as symptoms or side-effects associated with their disease, or the medications to treat it. Physicians can then tailor therapy to a patient's evolving needs based on that information, rather than on clinical assessments and patient-reported data alone.

As well as proprietary battery technology, the Percept™ RC DBS system features several other innovative features:

- Engineered for patient comfort, it's the world's smallest and thinnest dual-channel DBS device[9]. Low-profile design allows for a deeper implant depth and minimal visibility of the device.
- The Percept™ family is the only DBS therapy with MR conditional labeling that allows for 3T and 1.5T full-body MRI scans (without having to turn off DBS therapy)[10-13], providing patients access to cutting-edge medical imaging when they need it.
- It's designed to facilitate expanded capabilities, allowing the Percept™ RC devices of today to benefit from software updates of the future.

Percept™ RC is approved in the EU for the treatment of symptoms associated with Parkinson's Disease (PD), Essential Tremor, Primary Dystonia, and Epilepsy.

The Percept™ RC neurostimulator will be available in Western Europe beginning mid-December, and will launch in additional regions based on local regulations.

It is also available in Japan and under review by the U.S. Food and Drug Administration.

About Medtronic DBS Therapy

DBS therapy is currently approved in many locations around the world, including the United States and Europe, for the treatment of recent and longer-standing Parkinson's disease, Essential Tremor, Primary Dystonia, and the disabling symptoms of Epilepsy.

DBS therapy uses a surgically implanted medical device, similar to a cardiac pacemaker, to deliver electrical stimulation to precisely targeted areas of the brain as adjunctive treatment for several neurological disorders. Medtronic was the first in Europe to offer full-body MR Conditional DBS systems for patients to have safe scans anywhere on the body under certain conditions. Since 1987, more than 180,000 Medtronic DBS devices have been implanted worldwide for movement disorders and other indications.[14]

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the U.S. Securities and Exchange Commission. Actual results may differ materially from anticipated results.

References

1. As compared to Boston Scientific Vercise Genus™* P16. MP92328632-05 REV-A. As compared to St Jude Medical Infinity™* 7. IPG. ARTEN600150429 - B.
2. Implantable Pulse Generator Infinity™ IPG Clinician's Manual ARTEN600149416 A - St Jude Medical (US Version), accessed on 10/18/23
3. Percept™ PC B35200 Neurostimulator with BrainSense™ Technology–Implant Manual M982261A015 REV A– Medtronic
4. Vercise™ Deep Brain Stimulation Systems, Surgical Implant Manual. MP92328632-05 REV A, accessed 10/18/23
5. The sensing feature of the Percept™ PC and Percept™ RC system is intended for use in patients receiving DBS where chronically recorded bioelectric data may provide useful, objective information regarding patient clinical status. The majority of patients with Parkinson's disease have an identifiable signal. Signal may not be present or measurable in patients treated for essential tremor, dystonia, or epilepsy.
6. Model to calculate Medtronic DBS implants worldwide, Medtronic Internal Memo, September 5 2023
7. Weekly recharge means full depletion and recharge of the battery 0% to 100% every week.
8. For implant depths of up to 2 cm under normal conditions
9. As compared to Boston Scientific Vercise Genus™* R16 and Vercise Genus™* P16. MP92328632-05 REV-A. As compared to St. Jude Medical Infinity™* 5/7 IPG. ARTEN600150429 – B
10. Under specific conditions. Refer to product labeling for full list of conditions: https://manuals.medtronic.com/manuals/mri/region
11. ImageReady™ MRI Guidelines for Boston Scientific Deep Brain Stimulation Systems – 92195369-01, accessed on 10/18/2023
12. MRI Procedure Information for Abbott Medical™† MR Conditional Deep Brain Stimulation Systems – ARTEN600090482 A, accessed on 10/18/2023
13. MRI guidelines for Medtronic deep brain stimulation systems 37601 37602 37603 37612 B35200 B35300 – M929535A_a_092 https://manuals.medtronic.com/manuals/mri/region
14. · Model to calculate Medtronic DBS implants worldwide, Medtronic Internal Memo, September 5 2023.

NOTE: Medtronic DBS therapy is approved for four indications: Parkinson's disease, essential tremor, dystonia, and epilepsy. Indications vary by product, refer to product labeling for details.

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https://news.medtronic.com/2023-12-05-Medtronic-receives-CE-Mark-for-the-Percept-RC-rechargeable-DBS-neurostimulator-with-BrainSense-technology