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Medtronic receives approval for Symplicity Spyral™ Renal Denervation System in Japan

Japan is now the 77th country to receive regulatory approval for the Symplicity Spyral Renal Denervation System

Medtronic, a global leader in healthcare technology, today announced it received approval in Japan from the Pharmaceuticals and Medical Devices Agency (PMDA) for its Symplicity Spyral™ renal denervation (RDN) system, also known as the Symplicity™ blood pressure procedure for the treatment of resistant hypertension. The company will now initiate the process to obtain approval for insurance coverage.

In Japan, hypertension is a significant health concern, affecting approximately 43 million adults.[1] Despite widespread awareness, only about 60% of those diagnosed with high blood pressure receive treatment, and just under half of those treated achieve adequate blood pressure control.[2] These figures highlight the ongoing need for accessible and innovative interventions that can complement medication and lifestyle modifications to improve outcomes for patients with hypertension.

The Symplicity blood pressure procedure is an innovative, minimally invasive procedure that uses a single thin tube to deliver radiofrequency energy to calm the nerves near the kidneys that can become overactive and cause elevated blood pressure. After sedation, the doctor inserts a single thin tube (also known as a catheter) into the artery leading to the kidney. Once the tube is in place, the doctor administers energy to the system to calm the excessive activity of the nerves connected to the kidney. The device is removed, leaving no implant behind.

“As hypertension continues to pose a growing health challenge in Japan, the demand for advanced and alternative treatment options is becoming increasingly critical, especially for Japan’s aging population,” stated Jason Weidman, senior vice president and president of the Coronary and Renal Denervation business within the Cardiovascular Portfolio at Medtronic. “This year marks 50 years of Medtronic serving patients in Japan. The recent approval by the PMDA underscores our dedication to advancing healthcare innovation and delivering transformative therapies to those in need. We are excited to continue our momentum and leadership in the RDN space by expanding patient and physician access to the Symplicity blood pressure procedure.”

Medtronic clinical trials, including the SPYRAL HTN-ON MED study, showed 24-month office systolic blood pressure reduction of 17.4 mmHg (Spyral patients) through two years and significantly greater reduction versus sham.[3] The SPYRAL HTN clinical program has the longest and largest real-world registry[4] and the largest dataset

showing long-term reductions without the need for additional medication.[4-5]

The Medtronic SPYRAL HTN global clinical program is the most comprehensive clinical program studying RDN in more than 5,000 patients in the presence and absence of medication, and with high baseline cardiovascular risk, and is backed by experience in over 30,000 patients globally.[6-13]

The Symplicity Spyral Renal Denervation System is approved for commercial use in over 75 countries around the world.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, 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 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, visit www.Medtronic.com and follow @Medtronic on LinkedIn.

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

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