MAY 6, 2024

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

Symplicity Spyral is the first renal denervation technology to be approved by the National Medical Products Administration; new, innovative, minimally invasive procedure uses radiofrequency energy to help reduce high blood pressure

Medtronic today announced it received approval from the National Medical Products Administration (NMPA) in China for its Symplicity Spyral™ renal denervation (RDN) system, also known as the Symplicity™ blood pressure procedure. Symplicity Spyral is the first RDN system in China to receive NMPA approval. The company intends to go through the provincial registration process and expects sales of Symplicity Spyral in China to be modest in the short-term.



Hypertension is one of the most prominent public health challenges in China, with over 245 million people affected by the condition.[1] Further, only 13.8% of those living with hypertension in China have their condition under control.[2] Worldwide, control rates remain low, despite available medications and lifestyle interventions. These challenges speak to the possibility that patients may benefit from an adjunctive treatment option to better manage their blood pressure.

This NMPA approval milestone comes shortly after Medtronic announced both the approval from the U.S. Food and Drug Administration for the Symplicity Spyral system as well as the launch of the technology in India and Canada. These achievements reinforce Medtronic's commitment to expand global access to this technology for individuals with hypertension. The Symplicity Spyral system also recently received approval under the Greater Bay Area policy in China to commercially sell the system to hospitals in the Greater Bay Area.

The Symplicity blood pressure procedure is an innovative, minimally invasive procedure that delivers 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 (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 tube is removed, leaving no implant behind.

"As the leader in renal denervation, we are looking forward to bringing the Symplicity blood pressure procedure to China, where high blood pressure rates continue to increase," said Jason Weidman, senior vice president and president of the Coronary and Renal Denervation business within the Cardiovascular Portfolio at Medtronic. "As these rates continue to climb, the need for innovative, alternative treatments is strong. The Symplicity procedure can provide people in China with another potential option when seeking high blood pressure solutions, complementing lifestyle modifications and medication."

Data have shown that small blood pressure reductions significantly reduce cardiovascular risk. Decreasing blood pressure by 10 mmHg leads to a 20% relative risk reduction of major cardiovascular events.[3]

Symplicity Spyral, one of the most thoroughly tested cardiovascular interventional devices coming to market, is backed by experience in more than 25,000 patients globally.[4] The procedure showed:

- Mean reduction in patients' office-based systolic blood pressure (OSBP) of 9 mmHg at three months (OFF MED), 9.9 mmHg at six months (ON MED), and 18 mmHg (OSBP) at three years, with sustained blood pressure reductions in more than 1,500 patients. [5-11]
- Very low rates of adverse events, making for a safe procedure.[5-11]

Symplicity also demonstrated improved blood pressure control with significantly more time in treatment range after radiofrequency RDN when compared to sham through three years. [12]

Currently limited for investigational use in Japan, the Symplicity Spyral Renal Denervation System is approved for commercial use in more than 70 countries around the world.

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 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 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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https://news.medtronic.com/Medtronic-receives-approval-for-Symplicity-Spyral-TM-Renal-Denervation-System-in-China