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Medtronic treats first U.S. patient in Global SYMPLICITY Registry DEFINE Study

Large, international registry designed to expand real-world data for Symplicity blood pressure procedure for uncontrolled hypertension

Medtronic today announced the first U.S. patient treated in the Global SYMPLICITY Registry (GSR) DEFINE clinical trial, documenting the safety and effectiveness of the Symplicity™ Spyral renal denervation (RDN) system in a real-world setting. The first procedure was performed by Dr. Stan Thornton of Thomas Hospital, an affiliate of Infirmary Health in Fairhope, Alabama.

“The first patient enrolled in the U.S. expansion of the GSR-DEFINE registry marks a major milestone for the commercial rollout of the Symplicity Spyral RDN system,” said Jason Weidman, senior vice president and president of the Coronary & Renal Denervation business, which is part of the Cardiovascular Portfolio at Medtronic. “We are committed to generating valuable real-world evidence and supporting our mission to make this breakthrough procedure available to the people who need it most.”

The GSR-DEFINE trial is an extension of the Global SYMPLICITY Registry, the largest study documenting the long-term safety and effectiveness of the Symplicity Spyral RDN system in a real-world setting in patients with uncontrolled hypertension. At the recent EuroPCR conference in Paris, Medtronic reported that GSR showed three-year declines in office systolic blood pressure of 16.3 mm Hg in 1,450 patients evaluated from outside the U.S. [1] With over 4,000 patients already enrolled outside of the U.S., GSR-DEFINE is a prospective, all-comer observational study in 251 sites across 55 countries including 5,000 patients globally.

“The U.S. GSR-DEFINE study builds on the Global SYMPLICITY Registry with the goal of enhancing our understanding of how renal denervation can improve outcomes for U.S. patients with uncontrolled hypertension in everyday clinical practice,” said Stan Thornton, MD, Cardiologist at Cardiology Associates at Thomas Hospital and Principal Investigator for the U.S. GSR DEFINE registry study. “We are proud to begin enrolling patients in the trial and treating patients with the Symplicity blood pressure procedure – a promising solution for millions worldwide in need of alternative solutions.”

Hypertension, or high blood pressure, impacts more than 1 billion adults worldwide, and is the leading modifiable cause of heart attack, stroke, and death.[2] Despite available treatment with medications and lifestyle changes, blood pressure remains uncontrolled for many patients. Nearly 80% of adults with hypertension do not have it

under control[3] and half of hypertension patients become non-adherent to medication within one year.[2-4]

The Symplicity RDN 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 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, visit www.Medtronic.com and follow 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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1 Mahfoud F, et al. EuroPCR 2025. Results include Symplicity Spyral and Flex catheters

2 WHO. Hypertension fact sheet. September 13, 2019. Available at: https://www.who.int/news-room/fact-sheets/detail/hypertension. Accessed February 15, 2022.

3 Mahfoud F, Kandzari DE, Kario K, et al. Long-term efficacy and safety of renal denervation in the presence of antihypertensive drugs (SPYRAL HTN-ON MED): a randomized, sham-controlled trial. The Lancet. 2022; 399:1401-1410.

4 Bhatt, D. et al, Long-term outcomes after catheter-based renal artery denervation for resistant hypertension: final follow-up of the randomised SYMPLICITY HTN-3 Trial. The Lancet. September 18, 2022. DOI: https://doi.org/10.1016/S0140-6736(opens new window)(22)01787-1.

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