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Six-month SPYRAL AFFIRM results from Medtronic demonstrate blood pressure reductions in high-risk cardiovascular patients

Medtronic also announced completion of enrollment in SPYRAL AFFIRM, which aims to build robust real-world evidence across traditionally underserved patient populations

Medtronic plc, a global leader in healthcare technology, today announced the completion of enrollment and the first results from the High Cardiovascular Risk Patient Cohort of the SPYRAL AFFIRM study. This first report demonstrated significant, safe, and sustained blood pressure reductions with the Symplicity™ Spyral renal denervation (RDN) system, with no increase in anti-hypertensive medication use at six months. The data was presented today as Featured Clinical Research during the Transcatheter Cardiovascular Therapeutics (TCT) 2025 conference.

Data from a cohort of 210 patients from 59 sites across Europe, Australia and the United States demonstrated significant reductions in both home and office systolic blood pressure (SBP) across multiple high-risk subgroups, including those with isolated systolic hypertension (ISH), diabetes mellitus (DM), and chronic kidney disease (CKD), with no increase in anti-hypertensive medication use. Additionally, the number of prescribed anti-hypertensive medications remained stable across all groups, and no major safety events were observed, further validating the safety of the Symplicity blood pressure procedure in high-risk patients.

“This first results from the SPYRAL AFFIRM study demonstrates significant, safe, and sustained blood pressure reductions in a high cardiovascular risk patient population that has limited therapeutic options and yet a higher likelihood of adverse events,” said Felix Mahfoud, MD, cardiologist at Basel University Heart Center, Switzerland and presenting author of the SPYRAL AFFIRM study. “Seeing positive outcomes in this population underlines why renal denervation is recommended as an adjunctive therapy in U.S. and European hypertension guidelines, helping to reduce blood pressure and improve long-term cardiovascular outcomes.”

At six months, high-risk cardiovascular patients treated with the Symplicity Spyral RDN system in this first report demonstrated clinically meaningful and statistically significant reductions in blood pressure, for readings both in-office and at-home at six months:

- DM group: −13.3 mmHg (office) and −5.9 mmHg (home)

- ISH group: −10.6 mmHg (office) and −4.6 mmHg (home)
- CKD group: −19.3 mmHg (office) and −5.4 mmHg (home)

Additionally, Medtronic announced completion of enrollment of the full cohort of the SPYRAL AFFIRM study, adding to the body of evidence for Symplicity Spyral RDN system. The SPYRAL AFFIRM study is a prospective, international, multicenter, single-arm trial evaluating the safety and efficacy of the Symplicity Spyral RDN system in a real-world cohort of 987 patients across 100 sites, with more than 50 percent of participants enrolled in the U.S.

"Completing enrollment in the SPYRAL AFFIRM study reinforces our commitment to building the most robust body of real-world evidence in the field of renal denervation," said Jason Weidman, senior vice president and president of the Coronary and Renal Denervation business within the Cardiovascular portfolio at Medtronic. 'Specifically, this study will allow us to evaluate the technology across clinically diverse and traditionally underserved patient populations – like high cardiovascular risk patients – whose blood pressure remains uncontrolled despite medication and lifestyle modifications."

The Symplicity RDN system is approved for commercial use in nearly 80 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 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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