Medtronic News

TCT26: Medtronic Symplicity blood pressure procedure shows significant blood pressure drops in SPYRAL AFFIRM real-world study

Nearly nine out of 10 patients experienced a clinical benefit at six months

Medtronic receives FDA approval for U.S. labeling update to Symplicity blood pressure procedure, expanding clinical evidence informing treatment options

GALWAY, Ireland and SAN DIEGO, Nov. 3, 2026 /PRNewswire/ -- Medtronic plc, a global leader in healthcare technology, today announced primary endpoint results from the SPYRAL AFFIRM post-approval study of the Symplicity Spyral™ renal denervation (RDN) system. The study showed statistically significant and clinically meaningful blood pressure reductions at six months, including office, home, and 24-hour ambulatory blood pressure, with no increase in antihypertensive medications. The findings were presented as late-breaking data at the Transcatheter Cardiovascular Therapeutics (TCT) 2026 annual meeting and simultaneously published in *Circulation Cardiovascular Interventions*.

SPYRAL AFFIRM is a prospective, multicenter, single-arm study designed with the United States (U.S.) Food and Drug Administration (FDA) to provide real-world evidence in patients with uncontrolled hypertension treated in the U.S. across diverse patient populations and clinically relevant subgroups, including women, Black American and Hispanic patients, and patients 65 and older. Six-month results in the U.S. primary endpoint cohort were compared with a prespecified performance goal.

At six months, the data showed:

- Patients treated with Symplicity Spyral had significant reductions in blood pressure compared with baseline:
    - Office Systolic Blood Pressure (OSBP): -18.2 ± 22.0 mmHg ($p<0.0001$)
    - Home blood pressure: -9.4 ± 13.8 mmHg ($p<0.0001$)
    - 24-hour Ambulatory Blood Pressure (ABPM): -9.7 ± 16.8 mmHg ($p<0.0001$)
- Similar blood pressure reductions were demonstrated in women, Black American and Hispanic patients, and patients 65 and older
- There was no increase in antihypertensive medications through six months (3.6 ± 2.0 medications, unchanged from baseline).
- The composite safety endpoint occurred in 2.1% of patients
- Nearly nine out of 10 patients experienced a clinical benefit at six months; a separate pooled analysis replicated this clinical benefit at three years.[1]

"The blood pressure reductions achieved with RDN in the AFFIRM study are transformative. In fact, they are within the range associated with a greater than 20% reduction in major adverse cardiovascular events, underscoring the clinical significance of these results," said Dr. David Kandzari, chief of Piedmont Heart Institute and Cardiovascular Services and lead principal investigator of the SPYRAL AFFIRM study. "Importantly, the study also demonstrated significant reductions in home blood pressure, offering insight into how patients are responding beyond the clinical setting and in their everyday lives. These findings reinforce the potential benefit of renal denervation in combination with lifestyle changes and medication for patients who continue to struggle with uncontrolled hypertension."

FDA approves Symplicity Spyral RDN system labeling update

Medtronic also announced it has received U.S. FDA approval to update the labeling for the Symplicity Spyral Multi-Electrode Renal Denervation Catheter. The updated labeling includes additional clinical data in patients with isolated systolic hypertension (ISH), chronic kidney disease (CKD) up to stage 3b (eGFR ≥30 mL/min/1.73 m^2), and type 2 diabetes, expanding the clinical evidence available to help inform treatment decisions in these patient groups. The indication for use remains unchanged,

allowing physicians and patients the full extent of options to manage their hypertension.

"Generating robust clinical evidence across broad and diverse patient populations remains central to our mission of improving outcomes for people living with hypertension," said Lara Barghout, senior vice president and president of Interventional Cardiology Therapies at Medtronic. "Backed by data from SPYRAL AFFIRM and our broader clinical program, this labeling update gives physicians additional information to guide treatment decisions for patients living with hypertension and high cardiovascular risk."

Evidence from the SPYRAL HTN clinical program, including SPYRAL AFFIRM and the Global SYMPLICITY Registry DEFINE, supported the labeling update.

The Symplicity RDN system is approved for commercial use in more than 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, 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.

[1] Kandzari et al, EuroIntervention. 2026;22:e1-e1 published online March 2026. DOI: 10.4244/EIJ-D-26-00161

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