

**MAR 10, 2026**

# CRT26: Medtronic renal denervation system demonstrates significant, safe, and sustained blood pressure-lowering effect through three years

*Nearly 9 out of 10 patients achieved meaningful health benefit in 3-year pooled analysis*

*Additionally, pooled analysis shows radiofrequency RDN cuts hypertensive emergencies by nearly half, saving potentially \$199 million per year in related healthcare costs*

*SPYRAL CARE to expand evidence for radiofrequency RDN in real-world Medicare patients*

March 10, 2026 – Medtronic, a global leader in healthcare technology, today announced new, long-term data for the Symplicity Spyral™ renal denervation (RDN) system. Results from a pooled analysis of the SPYRAL HTN Clinical Study Program demonstrate nearly nine out of 10 patients experience a clinical benefit – reductions in 24-hr ambulatory systolic blood pressure (ABPM), office-based systolic blood pressure (OSBP), or reduction of at least one antihypertensive medication – at three years. The late-breaking data were presented as part of the Cardiovascular Research Technologies (CRT) 2026 annual meeting.

“This late-breaking three-year data reinforces the durable and clinically meaningful impact of the Symplicity blood pressure procedure,” said Jason Weidman, senior vice president and president of the Coronary and Renal Denervation business within the Cardiovascular Portfolio at Medtronic. “We’re seeing sustained, significant reductions in blood pressure with Symplicity over time – an important validation of radiofrequency renal denervation as a long-term treatment strategy. As the body of evidence continues to grow, we remain confident in the role of Symplicity Spyral in setting the standard for safe, effective, and lasting blood pressure reductions across a broad spectrum of patients who need more than medication alone.”

Data from 2,137 patients were pooled from the Global SYMPLICITY Registry (GSR) DEFINE, SPYRAL First-In-Man, SPYRAL HTN-OFF MED, and -ON MED trials. The analysis aimed to determine the proportion of patients who experienced clinical benefit.

- Spyral treated patients had significant mean reductions in OSBP and ABPM at 3-years:
  - OSBP:  $-18.1 \pm 23.4$  mmHg compared with baseline ( $p < 0.0001$ )
  - 24-hour ABPM:  $-13.3 \pm 17.6$  mmHg compared with baseline ( $p < 0.0001$ )

- 88% of patients experienced either an OSBP reduction  $\geq 10$  mmHg, a 24-h ABPM reduction  $\geq 5$  mmHg, or a reduction of at least one antihypertensive medication at 3 years.
- Results demonstrated amplified BP reduction through three years with few adverse events.

The findings from the SPYRAL HTN Clinical Study Program trial have also been published in EuroIntervention Journal, a peer-reviewed journal in the field of percutaneous and surgical cardiovascular interventions.

“These results represent an important milestone in advancing clinician understanding of the long-term impact of radiofrequency renal denervation for patients with uncontrolled hypertension,” said Dr. David Kandzari, Chief of Piedmont Heart Institute and Cardiovascular Services and lead principal investigator of the SPYRAL HTN-ON MED trial. “We’re seeing sustained blood pressure reductions that get progressively better with time, without an increase in concomitant medication burden. The data also demonstrates the potential to reduce the number of hypertensive medications and simplify treatment protocols - an outcome that we know can make a meaningful difference for patients when it comes to treatment burden and their everyday life.”

### **Pooled Analysis: Symplicity Spyral reduces hypertensive urgencies with potential U.S. cost savings**

Medtronic also presented a pooled analysis of hypertensive urgencies for SPYRAL HTN-OFF MED, and -ON MED trials, showing hypertensive urgencies were 42% lower after radiofrequency RDN with the Symplicity Spyral device at two-years follow up. Hypertensive urgency is a common medical emergency, which can lead to progressive end-organ damage. In the study, the potential annual hypertensive urgency-related healthcare costs savings was approximately \$199 million per year, indicating radiofrequency RDN may have potential to help to significantly reduce hypertensive urgency-related healthcare costs in the U.S.

The pooled analysis included 703 patients analyzed as RF RDN (N=388) vs. sham (N=315) treated patients. Hypertensive urgency was defined in the pooled cohort as an office SBP  $\geq 180$  mmHg or office DBP  $\geq 120$  mmHg, with or without symptoms.

### **SPYRAL CARE to expand evidence for radiofrequency RDN in real-world Medicare patients**

Medtronic also presented the study design for the SPYRAL CARE study, an observational study of the Medicare population with uncontrolled hypertension, to provide real-world evidence for radiofrequency RDN in this patient population. The SPYRAL CARE Study was approved by the U.S. Centers for Medicare & Medicaid Services (CMS) following its final National Coverage Determination (NCD) on renal denervation.

The SPYRAL CARE study will analyze medical and prescription claims linked to electronic health records and evaluate change in OSBP and major cardiovascular events (non-fatal stroke, non-fatal myocardial infarction, and death) up to 2 years.

### **About the SPYRAL HTN Global Clinical Program**

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.<sup>1-8</sup> The Symplicity Spyral RDN system has demonstrated sustained and durable drops in blood pressure out to three years in randomized control and real-world registry trials.<sup>9-11</sup> Symplicity Spyral is the only commercially available RDN device with the breadth of

durable, consistent, long-term data and single catheter design.<sup>2, 3, 6, 8, 12</sup>

### **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](http://www.Medtronic.com) and follow us on [LinkedIn](https://www.linkedin.com/company/medtronic).

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

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<sup>1</sup> Medtronic data on file, RDN Catheter Historical Data, Feb 2025. Data includes both Symplicity Flex and Symplicity Spyral.

<sup>2</sup> Kandzari DE, Townsend RR, Kario K, et al. Safety and Efficacy of Renal Denervation in Patients Taking Antihypertensive Medications. *J Am Coll Cardiol*. 2023 Nov 7;82(19):1809-1823.

<sup>3</sup> Böhm M, Kario K, Kandzari DE, et al. Efficacy of catheter-based renal denervation in the absence of antihypertensive medications (SPYRAL HTN-OFF MED Pivotal): a multicentre, randomised, sham-controlled trial. *Lancet*. 2020 May 2;395(10234):1444-1451.

<sup>4</sup> Kario K, Ogawa H, Okumura K, et al. SYMPPLICITY HTN-Japan - first randomized controlled trial of catheter-based renal denervation in asian patients -. *Circ J*. 2015;79(6):1222-1229.

<sup>5</sup> Bhatt DL, Kandzari DE, O'Neill WW, et al. A controlled trial renal denervation for resistant hypertension. *N Engl J Med*. April 10, 2014;370(15):1393-1401.

<sup>6</sup> Townsend RR, Mahfoud F, Kandzari DE, et al. Catheter-based renal denervation in patients with uncontrolled hypertension in the absence of antihypertensive medications (SPYRAL HTN-OFFMED): a randomised, sham-controlled, proof-of-concept trial. *Lancet*. November 11, 2017;390(10108):2160-2170.

<sup>7</sup> Krum H, Schlaich MP, Sobotka PA, et al. Percutaneous renal denervation in patients with treatment-resistant hypertension: final 3-year report of the Symplicity HTN-1 study. *Lancet*. 2014;383(9917):622-629.

<sup>8</sup> Mahfoud F, Schlaich M, Schmieder RE, et al. Long-term outcomes in ESC guideline-recommended patients for RDN from Global SYMPPLICITY Registry DEFINE. *EuroPCR* 2025.

<sup>9</sup> Kandzari DE et al. Long-term Safety and Efficacy of Radiofrequency Renal Denervation in the Presence of Antihypertensive Drugs: 24-Month Results from the SPYRAL HTN-ON MED Randomized Trial. TCT 2024

<sup>10</sup> Bhatt, D. et al, Long-term outcomes after catheter-based renal artery denervation for resistant hypertension: final follow-up of the randomised SYMPPLICITY HTN-3 Trial. The Lancet. September 18, 2022. DOI: DOI: [10.1016/S0140-6736\(22\)01787-1](https://doi.org/10.1016/S0140-6736(22)01787-1)

<sup>11</sup> Mahfoud, F. et al. Outcomes Following Radiofrequency Renal Denervation According to Antihypertensive Medications: Subgroup Analysis of the Global SYMPPLICITY Registry DEFINE. Hypertension. August 2023; DOI: 10.1161/HYPERTENSIONAHA.123.21283.

<sup>12</sup> Mahfoud F, et al. Long-term outcomes in ESC guideline-recommended patients for RDN from Global SYMPPLICITY registry DEFINE. EuroPCR 2025

<https://news.medtronic.com/CRT26-Medtronic-renal-denervation-system-demonstrates-significant.-safe.-and-sustained-blood-pressure-lowering-effect-through-three-years>