

**MAR 28, 2026**

# ACC.26: Medtronic announces support for EMBRACE investigator-initiated study focused on high cardiovascular risk patients

EMBRACE trial to study renal denervation with the Symplicity Spyral™ system and percutaneous coronary intervention (PCI) in the same procedure In SPYRAL HTN ON and OFF MED trials, patients...

- *EMBRACE trial to study renal denervation with the Symplicity Spyral™ system and percutaneous coronary intervention (PCI) in the same procedure*
- *In SPYRAL HTN ON and OFF MED trials, patients receiving RDN had a significantly lower rate of hypertensive urgencies after radiofrequency RDN through three years compared to sham*

**March 28, 2026** – Medtronic, a global leader in healthcare technology, today announced the EMBRACE trial, led by Dr. Roxana Mehran, Professor of Medicine and Director of Interventional Cardiovascular Research and Clinical Trials at the Zena and Michael A. Wiener Cardiovascular Institute at the Icahn School of Medicine at Mount Sinai, and Dr. Felix Mahfoud, Professor of Cardiology at the University of Basel and Chief of Cardiology at the University Hospital Basel.

The **E**xpand **M**anagement of **B**lood pressure with **R**enal denervation in patients undergoing staged PCI for **A**dvanced **C**oronary artery disease **E** (EMBRACE) is a randomized, multicenter trial evaluating Symplicity Spyral™ renal denervation added to staged PCI versus staged PCI alone in patients with uncontrolled hypertension and multivessel coronary artery disease. The primary endpoint will be assessed at two years, with a total follow-up extending to three years. Uniquely, in this trial, clinical effectiveness with radiofrequency renal denervation will be assessed using a composite endpoint that includes cardiovascular death, stroke, myocardial infarction, and hospitalization for heart failure or hypertensive crisis, among others.

“Uncontrolled hypertension is a major driver of coronary artery disease progression and recurrent ischemic events,” said Jason Weidman, senior vice president and president of the Coronary and Renal Denervation business within the Cardiovascular Portfolio at Medtronic. “The EMBRACE study complements our robust clinical program to benefit complex patients with high blood pressure and coronary artery disease. These patients are called out in global guidelines as needing more aggressive hypertension management. Our physician-initiated studies, including the EMBRACE study, strongly reflect the priorities of the cardiovascular clinical community.”

The study will enroll 1,000 patients with multi-vessel disease and uncontrolled hypertension undergoing staged PCI and will take place across 55 sites in up to 20 countries including the United States, Europe and Asia.

“PCI is no longer the end of the journey - it’s the beginning of a broader strategy to address residual cardiovascular risk,” said Dr. Mehran. “Uncontrolled hypertension remains a key driver of recurrent events, and EMBRACE explores a potential ‘sweet spot’ where revascularization and renal denervation can be combined to move from intervention to prevention.”

This is an investigator-initiated study that is funded by Medtronic.

“Continuing to build on the evidence base of Symplicity, we are excited to partner with Dr. Mehran and Dr. Mahfoud for the EMBRACE trial to help understand if the approach will more aggressively bend the cardiovascular (CV) risk curve in high CV risk patients,” said Jason Fontana, PhD, vice president and general manager of Medtronic’s Renal Denervation business.

### **Reducing Hypertensive Urgency with Radiofrequency Renal Denervation through three years: Insights from the SPYRAL HTN ON and OFF MED trials**

Separately, Medtronic also announced new insights for the Symplicity Spyral™ renal denervation (RDN) system. Prof. Dr. Michael Böhm, director of the Klinik für Innere Medizin III and Chief of Cardiology at the University of the Saarland in Homburg/Saar in Germany, presented results from a pooled analysis of the SPYRAL HTN ON- and -OFF MED trials.

The pooled analysis of 388 patients randomized to RDN and 315 to sham control showed RDN patients had a significantly lower rate of hypertensive urgencies (40%) compared to sham control patients through three years.

Additionally:

- The cumulative mean hypertensive urgency incidence at 3 years was 0.21 vs 0.39 per patient in RDN vs Sham (HR 0.60 [95% CI:0.40, 0.90]) (p=0.014).
- RDN patients also had a statistically significant lower medication burden compared to sham at 3-years (3.7±4.3 vs 6.0±11.2; p=0.003).
- Assuming a treatment (RDN) adoption rate of 50%, the potential hypertensive urgency-related healthcare costs savings in the U.S. was approximately \$380 million USD per year.

“With the insights from our SPYRAL HTN ON-MED, OFF-MED trials, we are seeing additional clinically meaningful health system benefits of Symplicity Spyral, including fewer emergent hypertensive events and lower medication burden,” added Fontana. “This underscores the value to the health care system, with reductions in emergency department admissions for hypertensive events resulting in an estimated \$380 million per year in potential savings in the U.S.”

### **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 on [LinkedIn](#).

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