

**FEB 19, 2026**

# Medtronic Receives Reimbursement Approval for Symplicity Spyral™ Renal Denervation System in Japan

*Milestone expands patient access to the first and most studied renal denervation therapy for hypertension.*

**DUBLIN - February 19, 2026** - Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has granted reimbursement approval for the Symplicity Spyral™ renal denervation (RDN) system, also known as the Symplicity™ blood pressure procedure, for the treatment of resistant hypertension.

In Japan, hypertension is a significant health concern, affecting approximately 43 million adults.<sup>1</sup> Despite widespread awareness, only about 60% of those diagnosed with high blood pressure receive treatment, and just under half of those treated achieve adequate blood pressure control.<sup>2</sup> These figures highlight the ongoing need for accessible and innovative interventions that can complement medication and lifestyle modifications to improve outcomes for patients with hypertension.

"This decision enables broader access to a therapy that has been shown to provide sustained reductions in blood pressure and improve outcomes for patients with hypertension," said Jason Weidman, Senior Vice President and President, Coronary & Renal Denervation, Medtronic. "We are proud to continue our 50-year legacy of serving patients in Japan through innovation and collaboration."

The Symplicity blood pressure procedure is an innovative, minimally invasive procedure that uses a single thin tube to deliver radiofrequency energy to calm the nerves near the kidneys that can become overactive and cause elevated blood pressure. After sedation, the doctor inserts a single thin tube (also known as a catheter) into the artery leading to the kidney. Once the tube is in place, the doctor administers energy to the system to calm the excessive activity of the nerves connected to the kidney. The device is removed, leaving no implant behind.

Medtronic clinical trials, including the SPYRAL HTN-ON MED study, showed 24-month office systolic blood pressure reduction of 17.4 mmHg (Spyral patients) through two years and significantly greater reduction versus sham.<sup>1</sup> The SPYRAL HTN clinical program has the longest and largest real-world registry and the largest dataset showing long-term reductions without the need for additional medication.<sup>2</sup>

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>3-10</sup>

The Symplicity Spyril Renal Denervation System is approved for commercial use nearly 80 countries around the world.

## About Hypertension

Hypertension, or high blood pressure, is a global health crisis, and is the leading modifiable cause of heart attack, stroke, and death.<sup>11</sup> 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<sup>11</sup> and 50% of hypertension patients become non-adherent to medication within one year.<sup>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 (NYSE: MDT), visit [www.Medtronic.com](http://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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<sup>1</sup> Kandzari et al. *Circ Cardiovasc Interv.* 2025;18:e015194. DOI: 10.1161/CIRCINTERVENTIONS.125.015194

<sup>2</sup> Mahfoud F, Mancina G, Schmieder RE, et al. Outcomes Following Radiofrequency Renal Denervation According to Antihypertensive Medications: Subgroup Analysis of the Global SYMPLICITY Registry DEFINE. *Hypertension.* 2023 Aug ;80(8):1759-177.

<sup>3</sup> Medtronic data on file, RDN Catheter Historical Data, Feb 2025. Data includes both Symplicity Flex and Symplicity Spyril.

<sup>4</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>5</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>6</sup> Kario K, Ogawa H, Okumura K, et al. SYMPLICITY HTN-Japan - first randomized controlled trial of catheter-based renal denervation in asian patients -. *Circ J.* 2015;79(6):1222-1229.

<sup>7</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>8</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>9</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>10</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>11</sup> WHO. Hypertension fact sheet. September 25, 2025. Available at: <https://www.who.int/news-room/fact-sheets/detail/hypertension>.

<sup>12</sup> Berra E, Azizi M, Capron A, et al. A. Evaluation of Adherence Should Become an Integral Part of Assessment of Patients With Apparently Treatment-Resistant Hypertension. *Hypertension*. 2016 Aug;68(2):297-306.

<https://news.medtronic.com/Medtronic-Receives-Reimbursement-Approval-for-Symplicity-Spyral-TM-Renal-Denervation-System-in-Japan>