

Symlicity Spyral™ Renal Denervation System

Category:

Best Medical Technology

Company Name:

Medtronic

Product/Solution Name:

Symlicity Spyral™ Renal Denervation System

Compound/Tech Name:

Symlicity Spyral™ Renal Denervation System

Trade Name:

Symlicity Spyral™ Renal Denervation System

Corporate Name:

Medtronic

Date of Approval:

2023-11-17

Indications:

To reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure

Therapeutic Areas:

Hypertension

General Information File Document upload:

N/A

Background information and need for drug / device:

The Issue: The Growing High Blood Pressure Epidemic

Nearly half of U.S. adults experience high blood pressure or hypertension. In 2021, it was a primary or contributing cause of almost 700,000 deaths in the U.S. as the condition increases the risk of heart attacks and strokes. High blood pressure affects men and women, young and old, people who are fit, people managing multiple health issues, and many others. Hypertension also contributes significant avoidable healthcare costs to the U.S. healthcare system - more than \$18 billion each year.

More than 75% of people don't have their high blood pressure under control despite lifestyle or medical therapy - highlighting the need for alternative solutions. Yet, little innovation in the treatment of hypertension has occurred in the past two decades - until now.

Earlier, the standard of care for hypertension focused on lifestyle changes (like diet and exercise) and medications, which for many people are not enough. About 50% of patients become non-adherent to medications after one year. Even minor reductions in high blood pressure can have a major impact on one's health. For example, a decrease in mean office systolic blood pressure by 10 millimeters of mercury (mmHg) can lead to a 20% lower chance of experiencing a hypertension-related health issue like stroke or heart failure.

The Solution: New Option for Patients with Uncontrolled High Blood Pressure

Medtronic recognized this tremendous unmet patient need and made it a priority to address it through rigorous clinical studies, groundbreaking technology and overall tenacity that outmatched all competitors. More than 15 years of clinical research and product development led to an innovative solution, ushering in a new era in hypertension care - the Symplicity Spyral™ renal denervation (RDN) system.

Symplicity Spyral is the first catheter-based approach using radiofrequency energy that complements medications and lifestyle modifications to help reduce blood pressure. The device leverages a single, minimally invasive procedure that delivers radiofrequency energy to nerves near the kidneys that can become overactive and contribute to high blood pressure. It is typically performed in one day on an outpatient basis.

The system was approved by the U.S. FDA in November 2023, the National Medical Products Administration (China) and Health Canada license in 2024 and has had CE Mark since 2013. More than 30,000 patients have been treated globally with Symplicity.

Meeting an Unmet Need: New Advancements in the Path to Reimbursement

In the last year, Medtronic has made headway getting Symplicity in major centers across the US and is now activating larger health systems.

In November 2024, the Centers for Medicare & Medicaid Services (CMS) granted transitional pass-through (TPT) payment for Symplicity Spyral, under the Medicare Hospital Outpatient Prospective Payment System - a qualification very few technologies achieve. Most recently, CMS opened a national coverage analysis (NCA) on RDN, which will allow the agency to review and develop a national Medicare coverage policy for RDN procedures for patients with hypertension.

Background File Document upload:

[MDT RDN FDA APPROVAL PRESS RELEASE.pdf](#)

History of the development of the solution/product:

Medtronic's innovation journey toward developing the Symplicity blood pressure procedure started in 2009 when the company acted upon a quickly developed proposal to leverage published promising clinical results of a renal denervation device from a startup, Adrian. Experts from several operating units unified to evaluate any existing Medtronic technology that might be applicable, and a team of engineering all-stars developed an RDN research lab with encouraging early results. In 2021, Medtronic announced they were buying the startup that inspired the project, so the company now had four simultaneous efforts underway to develop RDN. Julie Trudel, Ph.D., who served as the senior program manager at the time, spearheaded the dive into renal denervation technology and led efforts to further the acquired technology, SMERF (Simultaneous Multi-Electrode Radio Frequency). With significant research and combined designs from Medtronic and the original startup prototype came Medtronic's first device-based procedure to lower high blood pressure - known as Symplicity Spyral.

Throughout the development process of Symplicity Spyral, building a body of strong, rigorous data was foundational. Fast forward to 2020, Symplicity Spyral received the FDA's breakthrough device designation based on data from the SPYRAL HTN clinical program. The landmark FDA approval of Symplicity in November 2023 represented the culmination of rigorous clinical trials, including long-term, sham-controlled studies in the presence and absence of medication, and the largest real-world study. It has proven to be safe and effective with a significant mean reduction of greater than nine mmHg in office systolic blood pressure in patients on and off medications at primary endpoint follow-up in multiple clinical trials and less than 0.4% major adverse events at composite endpoint. Data have also shown a sustained 18 mmHg mean reduction in office systolic blood pressure in real-world patients at three years, demonstrating sustained reductions in more than 1,500 patients.

"The number one lesson when you talk about a long journey like this is one of

perseverance. It's never a straight-line path to bring new technology to market, and in particular developing a new therapy. We went along that path. We're at a great spot, and I couldn't be more thrilled,\" said Jason Weidman, Medtronic Senior Vice President and President of Coronary and RDN.

Development File Document upload:

[MDT RDN Clinical Data.pdf](#)

[MDT RDN Clinical Data.pdf](#)

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

Using a first-of-its-kind design, Symplicity successfully works to reduce high blood pressure numbers, creating the opportunity for millions of patients to regain peace of mind with a safe and effective treatment option.

The innovation behind Symplicity Spyral stems primarily from the use of first-of-its-kind radiofrequency energy. During the Medtronic RDN procedure, an interventional cardiologist uses a catheter to send radiofrequency (heat) energy to the renal arteries, which are the blood vessels supplying blood to the kidneys. This radiofrequency energy disables or ablates renal nerves without damaging the arteries. Precisely controlled and targeted radiofrequency is the ideal energy source for a renal denervation procedure as it has high specificity for renal nerves based on the anatomy and tissue conductive properties.

The unique design of Symplicity Spyral also differentiates it from other solutions on the market. The catheter possesses an easy-to-use, plug-and-play design with a non-occlusive pattern to allow continuous renal artery blood flow while protecting the vessel walls from thermal damage. Furthermore, it's a one-size-fits-most device to treat virtually all patients' vessel sizes from 3 mm to 8mm. In clinical trials evaluating Symplicity Spyral, only about 3% of patients were excluded from the study for anatomical exclusions, which varies greatly from other devices and trials evaluating treatment options for hypertension.

The \"always-on\" effects of the Symplicity™ blood pressure procedure work 24/7, even during nighttime and early mornings when blood pressure can spike. For some patients, this could mean there is no device to monitor or additional pills to remember - potentially providing millions of patients with greater peace of mind that represents a turning point in hypertension care.

In August 2024, the European Society of Cardiology (ESC) released updated guidelines, which upgraded RDN as a class IIb recommendation, providing a safe and effective complementary care option for patients with uncontrolled and resistant hypertension -

underscoring the role of the Symplicity blood pressure procedure for hypertension care.

Innovation File Document upload:

MDT RDN Brochure.pdf

Please provide appropriate references (PubMed, Abstract, Website):

Website:

<https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/renal-denervation.html>

Clinical Data:

SPYRAL HTN-OFF MED Trial:

<https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/renal-denervation/clinical-evidence.html#spyral-htn-off>

SPYRAL HTN-ON MED Trial:

<https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/renal-denervation/clinical-evidence.html#spyral-htn-on>

Global Symplicity Registry:

<https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/renal-denervation/clinical-evidence.html#global-symplicity>

References File Document upload:

N/A