

Medtronic

Symlicity Spyral™
renal denervation system

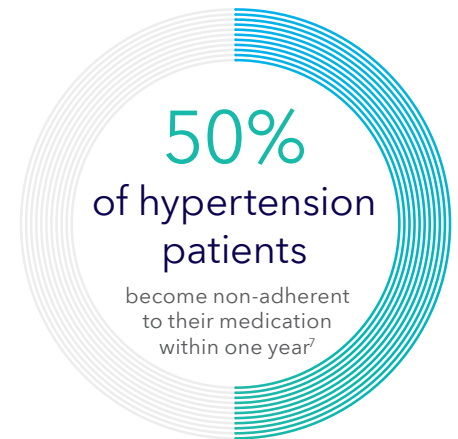
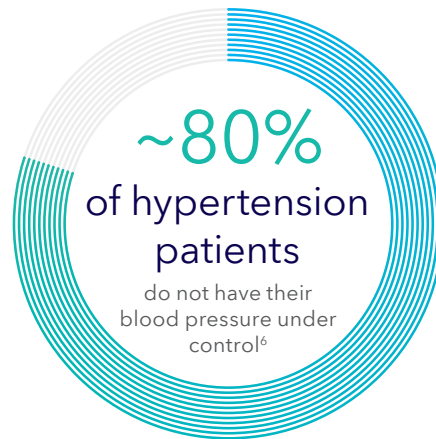
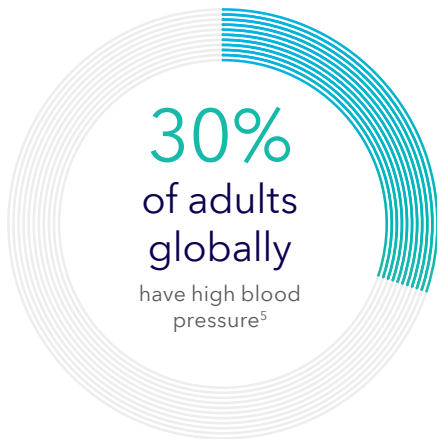


This is the
turning point
in hypertension care

The Symlicity™ blood pressure procedure delivers significant, safe, and sustained BP reductions.¹⁻⁴

When typical hypertension treatments aren't enough

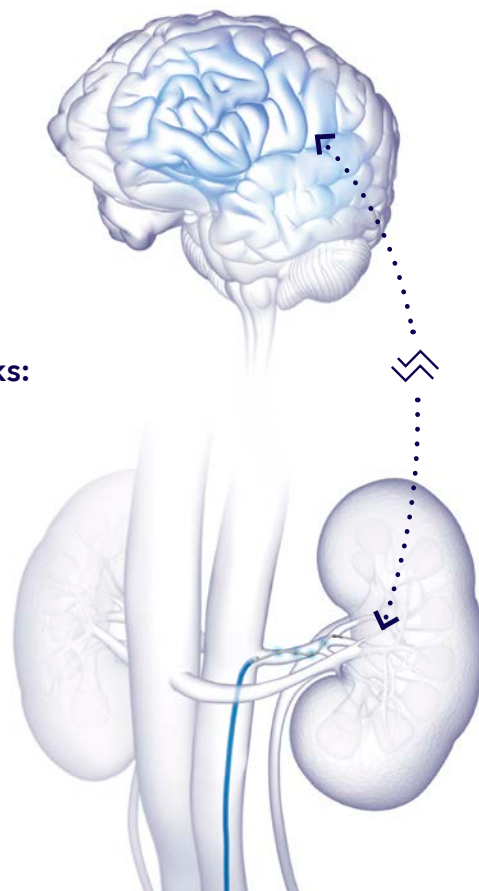
Lifestyle changes and medications have defined hypertension treatment, but they are not always enough to help patients achieve control.



Turn to a proven approach to treat hypertension

How renal denervation with Symplicity Spyral works:

- Supplies precisely controlled and targeted radiofrequency energy to the renal nerves⁸
- Safely disrupts the overactive sympathetic signaling between the kidneys and brain to reduce blood pressure⁸



Setting the standard in renal denervation

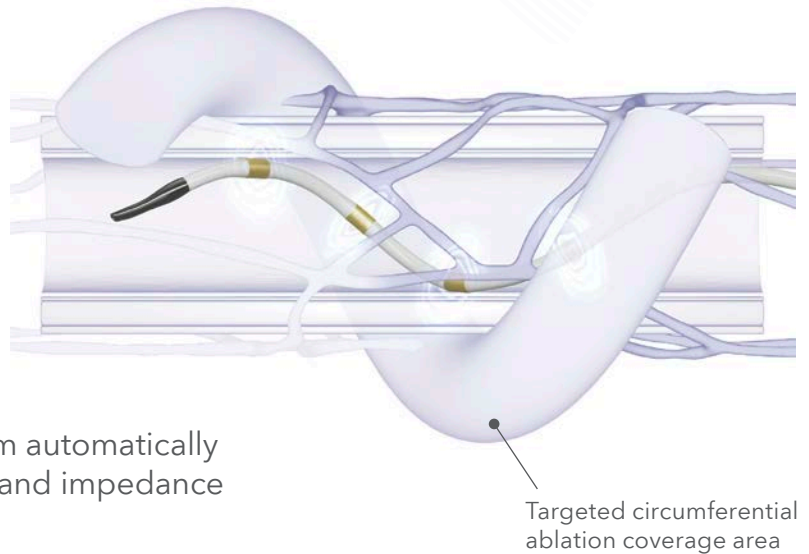
>25,000 patients treated globally with
the Symplicity RDN system⁹

Simple and versatile

- One catheter size fits vessels 3-8 mm¹⁰
- 4 F catheter,[†] compatible with 6 F guide catheter, 0.014" guidewire
- Easy-to-use, plug-and-play design
- Nonocclusive design allows for continuous blood flow to naturally protect the vessel wall⁸

Safe and precise

- Unique, real-time, and responsive algorithm automatically adjusts power by monitoring temperature and impedance for safe energy distribution⁸
- Multi-electrode, helical design covers four quadrants simultaneously for a circumferential ablation^{8,10}
- Radiofrequency energy preferentially heats fat tissue where renal nerves are located and avoids non-target structures¹¹
- Only Symplicity Spyrax allows for denervation throughout the renal anatomy, including the distal branches,¹⁰ where late arriving nerves are accessible and total nerve density is highest^{12,13}



Significant, safe, and sustained blood pressure reductions

>4,000 patients enrolled in the
global clinical program^{†1-3,14,15}

Significant

SPYRAL HTN-OFF MED¹

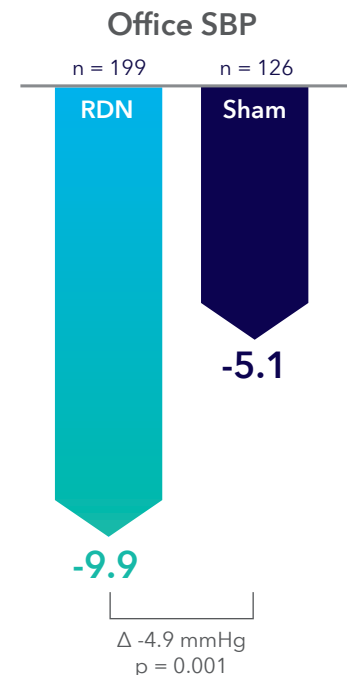
Pivotal Trial
Significant BP reduction in the
absence of medication at 3 months



24 hr ambulatory blood pressure
primary endpoint
-4.7 RDN vs. -0.6 sham, p < 0.001

SPYRAL HTN-ON MED²

Significant BP reductions with **20% lower
medication burden at 6 months** with RDN
(2.9 RDN vs. 3.5 sham, p = 0.04)



24 hr ambulatory blood pressure
primary endpoint
-6.5 RDN vs. -4.5 sham, p = 0.12

>9
mmHg

reduction in OSBP
in patients off and
on medications^{1,2}

Safe

Excellent safety profile

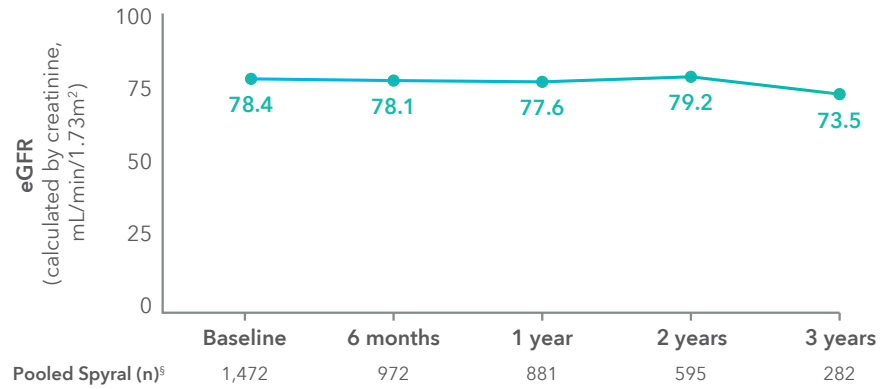
Pooled data from the SPYRAL HTN-OFF MED and SPYRAL HTN-ON MED trials indicated low incidence of procedural related and clinical adverse events.²

0.4%

major adverse event rate at composite endpoint, including no new incidence of renal artery stenosis (>70%) at 6 months²

Stable kidney function

Pooled data from the SPYRAL HTN-OFF MED and SPYRAL HTN-ON MED trials, Global SYMPPLICITY Registry, and proof-of-concept study showed minimal impact to kidney function at 3-year follow-up.¹⁶



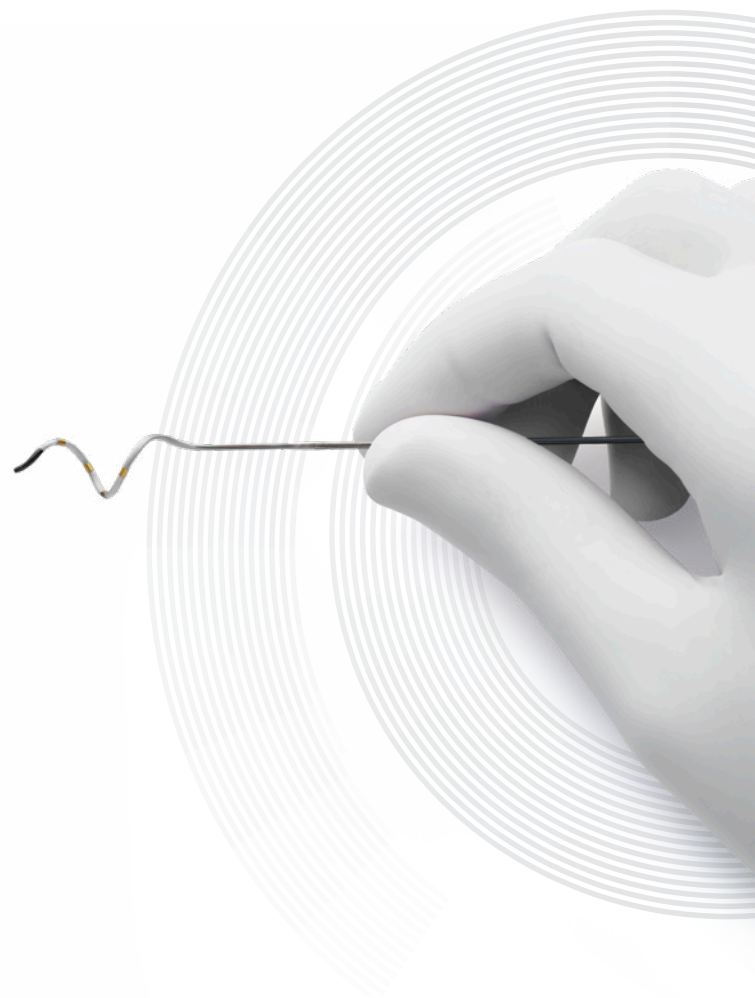
Sustained

Only the Symplicity RDN system has demonstrated sustained BP reductions **through 3 years in real-world patients.**¹⁷

18

mmHg

reduction in OSBP real-world patients at 3 years with the Symplicity Spyrals catheter, n = 267¹⁷



Recommended by cardiovascular experts

- > 20 guidelines and consensus statements from medical societies worldwide are shaping patient selection for renal denervation, including the Symplicity blood pressure procedure
- The European Society of Hypertension now recommends RDN as a safe and effective complementary hypertension treatment strategy¹⁸



Scan to view the ESH guidelines

Patient selection

Consider the Symplicity blood pressure procedure for patients who fit one or more of the following criteria:

- Uncontrolled BP, despite an optimal medication regimen
- Elevated cardiovascular risks: heart failure, coronary heart disease, atrial fibrillation, stroke, or diabetes
- Unwilling or unable to adhere to medication due to side effects or intolerance
- Willing to undergo a minimally invasive procedure



>50%
of patients

would be willing to consider an interventional approach to reduce BP¹⁹





Partners in care

Enhance your hypertension treatment strategies with:



Strategic collaboration designed to improve care for patients



Access to world-class referral, training, and education resources



Experienced field and support teams

Components and ordering information

RDN016 Symplicity Spyral multi-electrode renal denervation catheter: single-use RDN catheter for use only with the Symplicity G3 renal denervation RF generator
RDNG3A/RDN017 (as approved in your country) Symplicity G3 generator: reusable RF generator, power cable, remote control, and DVI-D output for use with the Symplicity Spyral catheter
RDN019 Mobile cart for Symplicity G3 generator (optional accessory)
0.014" Guidewire (non-hydrophilic with a supportive shaft and a floppy tip)
4 F catheter, [†] compatible with 6 F guide catheter (90 cm max length)
Dispersive Electrode for RDNG3A: Compatible with ValleyLab REM Polyhesive Adult Patient Return Electrode (Model E7507, E7507-DB)
Dispersive Electrode for RDN017: A disposable dispersive electrode with a molded connector specified for adult use that complies with IEC 60601-2-2 is required

[†]Catheter dimension of 0.052" is average diameter determined during design verification. Upper bound allowable is 0.061".

[‡]Study follow-up is ongoing. Data does not represent follow-up for all patients.

[§]Not all subjects analyzed have completed follow-up through 3 years. All available data included at the time of this analysis.

¹ 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*. May 2, 2020;395(10234):1444-1451.

² Kandzari DE. Renal denervation in the presence of anti-hypertensive medications: six-month results from the randomized, blinded, sham-controlled SPYRAL HTN-ON MED trial. Presented at AHA, November, 2022.

³ Mahfoud F, Mancía G, Schmieder R, et al. Renal Denervation in high-risk patients with hypertension. *J Am Coll Cardiol*. June 16, 2020;75(23):2879-2888.

⁴ Mahfoud F, Kandzari DE, Kario K, et al. Long-term efficacy and safety of renal denervation in the presence of antihypertensive drugs (SPYRAL HTN-ON MED): a randomised, sham-controlled trial. *Lancet*. April 9, 2022;399(10333):1401-1410.

⁵ NCD Risk Factor Collaboration (NCD-RisC). Worldwide trends in hypertension prevalence and progress in treatment and control from 1990 to 2019: a pooled analysis of 1201 population-representative studies with 104 million participants. *Lancet*. September 11, 2021;398(10304):957-980.

⁶ World Health Organization. Hypertension fact sheet. <https://www.who.int/news-room/fact-sheets/detail/hypertension>. Accessed August 23, 2023.

⁷ Jung O, Gechter JL, Wunder C, et al. Resistant hypertension? Assessment of adherence by toxicological urine analysis. *J Hypertens*. April 2013;31(4):766-774.

⁸ Coates P, Tunev S, Trudel J, Hettrick DA. Time, temperature, power, and impedance considerations for radiofrequency catheter renal denervation. *Cardiovasc Revasc Med*. September 2022;42:171-177.

⁹ Medtronic data on file. RDN Catheter Historical Data, June 2023. Data includes both Symplicity Flex and Symplicity Spyral.

¹⁰ Medtronic Symplicity Spyral Instructions for Use.

¹¹ Sato Y, Sharp A, Mahfoud F, et al. Translational value of preclinical models for renal denervation: a histological comparison of human versus porcine renal nerve anatomy. *Eurointervention*. February 6, 2023;18(13):e1120-e1128.

¹² García-Touchard A, Marañillo E, Mompeo B, Sañudo JR. Microdissection of the human renal nervous system: Implications for performing renal denervation procedures. *Hypertension*. October 2020;76(4):1240-1246.

¹³ Struthoff H, Lauder L, Hohl M, et al. Histological examination of renal nerve distribution, density, and function in humans. *Eurointervention*. September 18, 2023;19(7):612-620.

¹⁴ 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-OFF MED): a randomised, sham-controlled, proof-of-concept trial. *Lancet*. November 11, 2017;390(10108):2160-2170.

¹⁵ Kandzari DE, Böhm M, Mahfoud F, et al. Effect of renal denervation on blood pressure in the presence of antihypertensive drugs: 6-month efficacy and safety results from the SPYRAL HTN-ON MED proof-of-concept randomised trial. *Lancet*. June 9, 2018;391(10137):2346-2355.

¹⁶ Symplicity Spyral Renal Denervation System. Sponsor Executive Summary. US FDA Circulatory Systems Devices Panel. Meeting date, August 23, 2023. Pg 121; Figure 58.

¹⁷ Medtronic data on file. Global Symplicity Registry clinical data snap, March 2023.

¹⁸ Mancía G, Kreutz R, Brunstrom M, et al. Authors/Task Force Members: 2023 ESH Guidelines for the management of arterial hypertension The Task Force for the management of arterial hypertension of the European Society of Hypertension Endorsed by the European Renal Association (ERA) and the International Society of Hypertension (ISH). *J Hypertens*. June 21, 2023.

¹⁹ Kandzari DE, Weber MA, Poulos C, et al. Patient Preferences for Pharmaceutical and Device-Based Treatments for Uncontrolled Hypertension: Discrete Choice Experiment. *Circ Cardiovasc Qual Outcomes*. January 2023;16(1):e008997.

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