Medtronic

Symplicity Spyral™

multi electrode renal denervation system†

This is the turning point

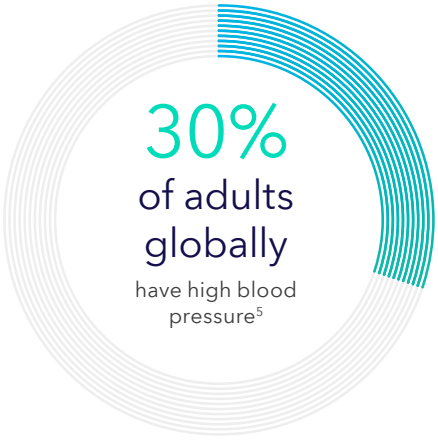
in hypertension care

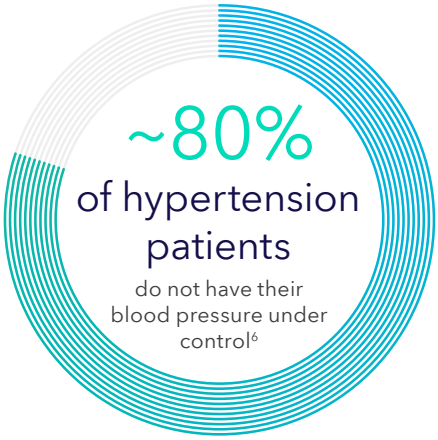
The Symplicity™ blood pressure procedure delivers significant, safe, and sustained BP reductions.[1-4]

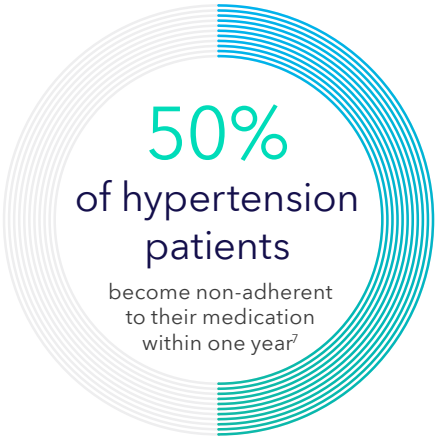
†Referred hereafter as Symplicity RDN System

When typical hypertension managements aren't enough

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

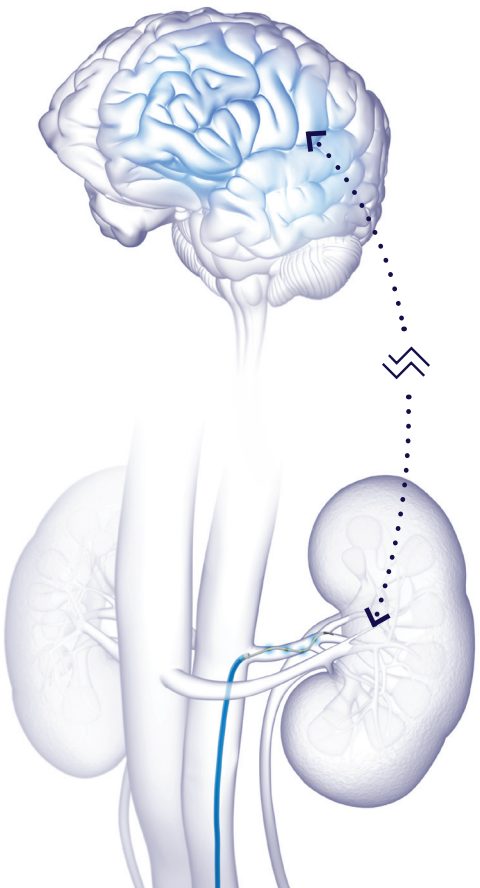






How renal denervation with Symplicity RDN System works:

- Supplies precisely controlled and targeted radiofrequency energy to the renal nerves[8]
- Safely disrupts the overactive sympathetic signaling between the kidneys and brain to reduce blood pressure[8]

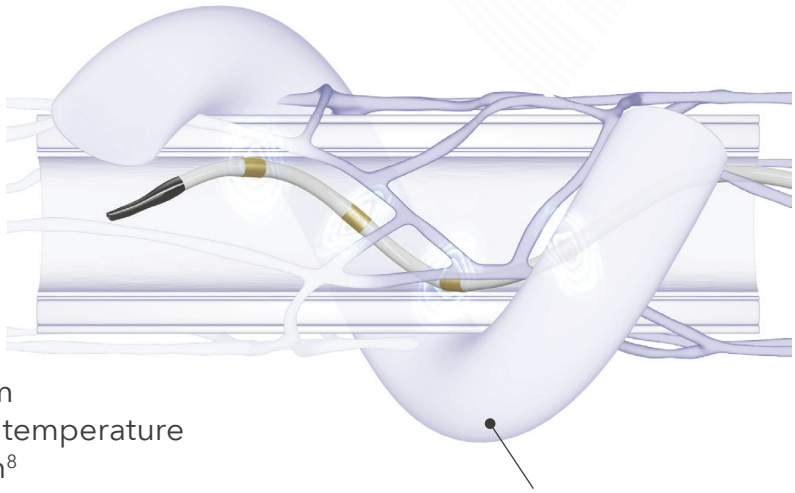


Setting the standard in renal denervation

>25,000 patients managed globally with the Symplicity RDN system[9]

Simple and versatile

- One catheter size fits vessels 3–8 mm[10]
- 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 wall[8]



Targeted circumferential ablation coverage area

Safe and precise

- Unique, real-time, and responsive algorithm automatically adjusts power by monitoring temperature and impedance for safe energy distribution[8]
- 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 structures[11]
- Only Symplicity RDN System 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]

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

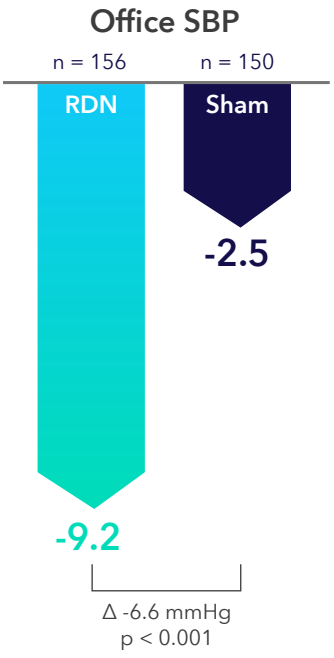
Significant, safe, and sustained blood pressure reductions[1–3,14,15]

>4,000 patients enrolled in the global clinical program[†1–3,14,15]

Significant

SPYRAL HTN-OFF MED[1]

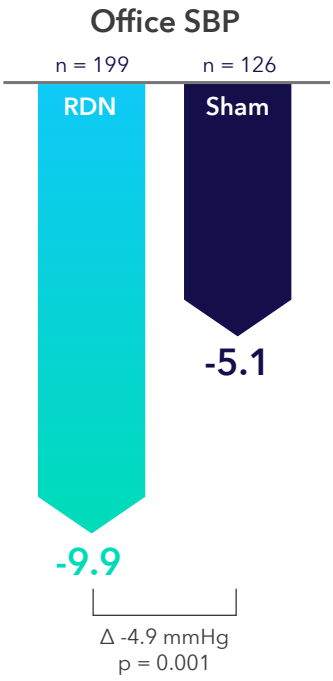
Pivotal Trial
Significant BP reduction in the **absence of medication** at 3 months



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

SPYRAL HTN-ON MED[2]

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]

†Study follow-up is ongoing. Data does not represent follow-up for all patients.

Safe

Excellent safety profile

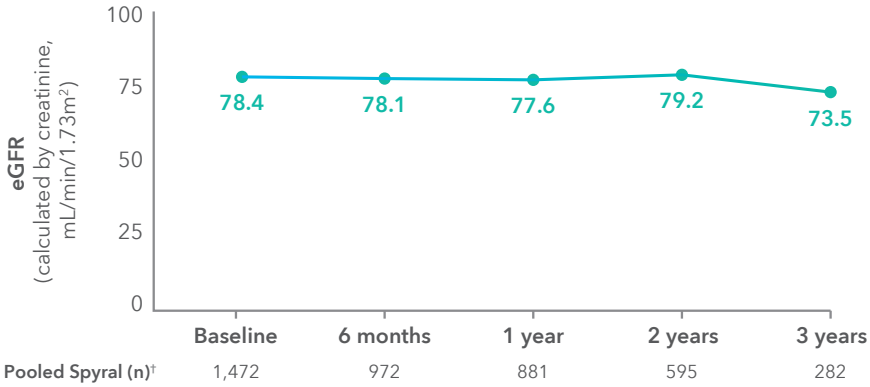
Pooled data from the **SPYRAL HTN-OFF MED** and **SPYRAL HTN-ON MED** trials indicated low incidence of procedural related and clinical adverse events.[2]

0.4%

major adverse event rate at composite endpoint, including no new incidence of renal artery stenosis (>70%) at 6 months[2]

Stable kidney function

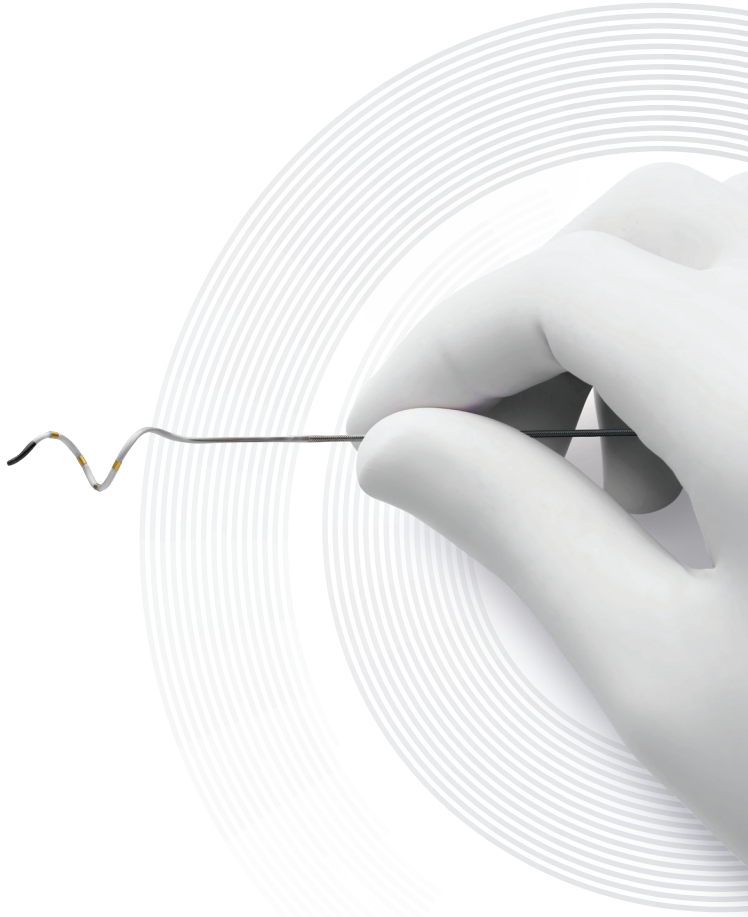
Pooled data from the **SPYRAL HTN-OFF MED** and **SPYRAL HTN-ON MED** trials, **Global SYMPLICITY Registry,** and **proof-of-concept study** showed minimal impact to kidney function at 3-year follow-up.[16]



Pooled Spyral (n)†	Baseline	6 months	1 year	2 years	3 years
	1,472	972	881	595	282

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 Spyral catheter, n = 267[17]

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

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 management strategy[18]

Scan to view the ESH guidelines†

>50%
of patients
would be willing to consider an interventional approach to reduce BP[19]

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

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Partners in care

Enhance your hypertension management 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 Symplicity G3 Renal Denervation RF 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 Electrode (Model E7507, E7507DB)

†Catheter dimension of 0.052" is average diameter determined during design verification. Upper bound allowable is 0.061".
‡Licensed as Symplicity RF G3 Generator Component: Remote Control

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.
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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.
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