

Medtronic

# Setting the standard in renal denervation

The Symplicity Spyral™ system is a complementary hypertension treatment option backed by evidence unmatched in scope, quantity and quality.

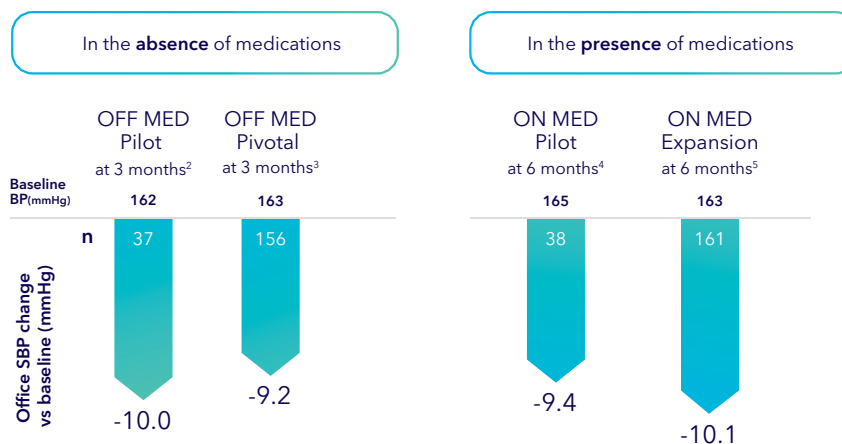
## Unmatched Evidence

>25,000 Patients treated globally with the Symplicity™ RDN system<sup>1</sup>

>4,000 Patients enrolled in the global clinical program<sup>2-6</sup>

## Significant

Consistent blood pressure reductions in 4 sham-controlled trials<sup>2-5</sup>



9

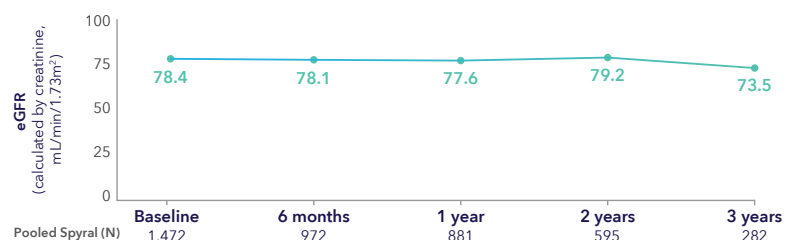
mmHg  
OSBP reduction in patients off and on medications<sup>2-5</sup>

## Safe

Excellent safety profile<sup>2-7,10</sup>

No new incidence of renal artery stenosis at 6 months<sup>5</sup>

Minimal decline in eGFR through 3 years<sup>10</sup>



## Sustained

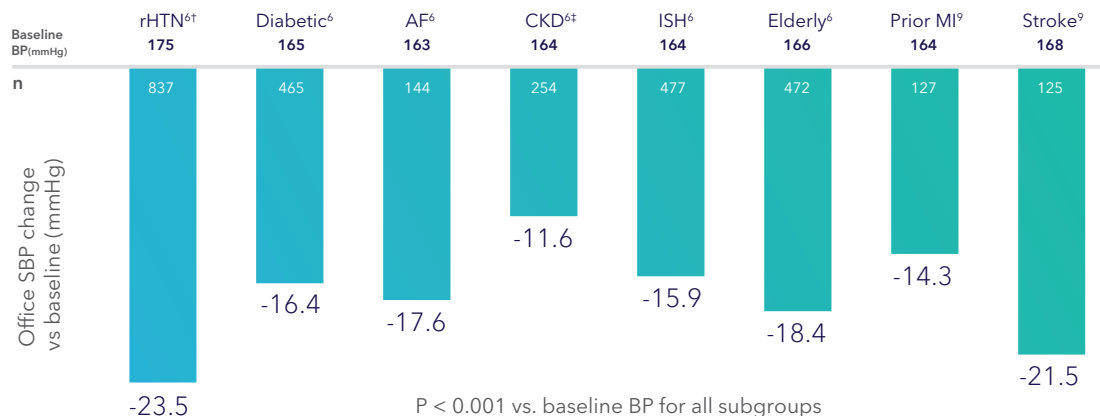
Only renal denervation with Symplicity Spyral™ System has demonstrated lasting blood pressure reductions **at 3 years**.<sup>6-8</sup>

18

mmHg  
reduction in OSBP at 3 years. n=267<sup>11</sup>

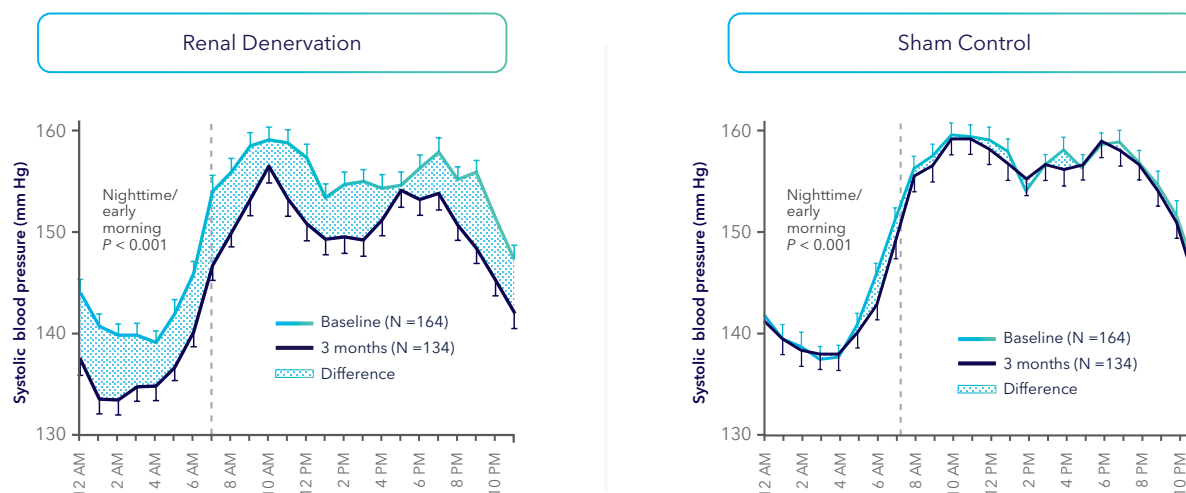
# Real-world results

Significant BP reductions across high-risk subgroups at 3 years in GSR



## Always on

RDN demonstrates 24-hr BP-lowering effect especially during high-risk night-time and early morning periods<sup>3</sup>



<sup>†</sup> Resistant hypertension defined as OSBP > 150 mmHg, ≥ 3 anti-hypertensive medications.

<sup>6</sup> CKD defined as eGFR < 60 ml/min/1.73 m<sup>2</sup>

<sup>1</sup> Medtronic Data on File. RDN Catheter Historic Data, June 2023. Data includes both Symplicity Flex and Symplicity Spyral.

<sup>2</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-OFF MED): a randomised, sham-controlled, proof-of-concept trial. *The Lancet*. 2017; 390(10108):2160-2170.

<sup>3</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. *The Lancet*. 2020; 395(10234): 1444-51.

<sup>4</sup> 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. *The Lancet*. 2018 Jun 9; 391(10137):2346-2355.

<sup>5</sup> 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 Nov. 2022.

<sup>6</sup> Mahfoud F, Mancia G, Schmieder R, et al. Renal Denervation in high-risk patients with hypertension. *J Am Coll Cardiol*. 2020; 75:2879-2888.

<sup>7</sup> Schlaich M, Mahfoud F, Williams B, et al. Long-Term Safety and Efficacy of Renal Denervation with the Symplicity Spyral Catheter in the Global SYMPLICITY Registry. *Am Soc Neph Kidney Week* 2021.

<sup>8</sup> 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. *The Lancet*. 2022; 399:1401-1410.

<sup>9</sup> Mahfoud F, et al. Blood pressure reduction after catheter-based renal denervation in patients with cardiovascular disease in the Global SYMPLICITY Registry. *ESH* 2022.

<sup>10</sup> Symplicity Spyral™ Renal Denervation System. Sponsor Executive Summary. US FDA Circulatory Systems Devices Panel. Meeting date August 23, 2023.

<sup>11</sup> Medtronic data on file, GSR DEFINE analysis, Apr 2023.

[medtronic.eu/RDN](https://www.medtronic.eu/RDN)

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