

Medtronic

Engineering the extraordinary

Transforming hypertension treatment

The Symplicity™ renal denervation system delivers clinically significant, safe, and sustained BP reductions¹⁻³

-18.7
mmHg

24-hour systolic
blood pressure
at 3 years⁴

A novel intervention for hypertension treatment

For decades, lifestyle changes and medication defined hypertension treatment. But they are not always enough to help patients achieve control.

50%
of hypertension patients

Become non-adherent to their medication within one year⁵

~80%
of hypertension patients

Do not have their blood pressure under control⁶

Supported by published clinical evidence unmatched in scope, quantity, and quality.

>4,000

patients in the global clinical program^{†8}

>7,000

patients in peer-reviewed research^{†8}

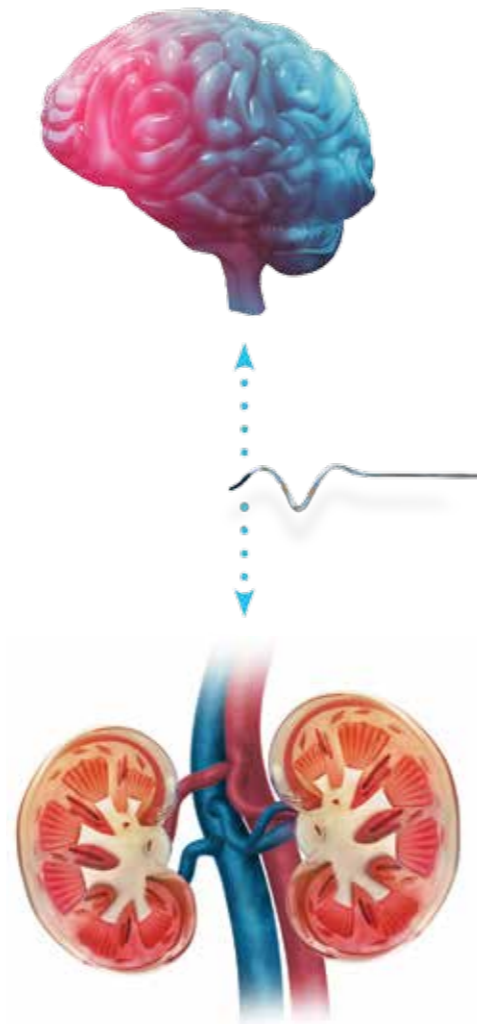
>20,000

patients treated^{†8}

Proven
to safely reduce
blood pressure¹

The Symplicity renal denervation system complements medication and lifestyle changes with an effective, evidence-based procedural approach to hypertension treatment.

- Supplies precisely controlled and targeted radiofrequency (RF) energy to the renal nerves⁷
- Safely disrupts the overactive sympathetic signaling between the kidneys and brain to reduce blood pressure⁷
- Delivers clinically significant, safe, and sustained blood pressure reductions¹⁻³



SPYRAL HTN-ON MED Pilot Study⁴

-18.7 mmHg

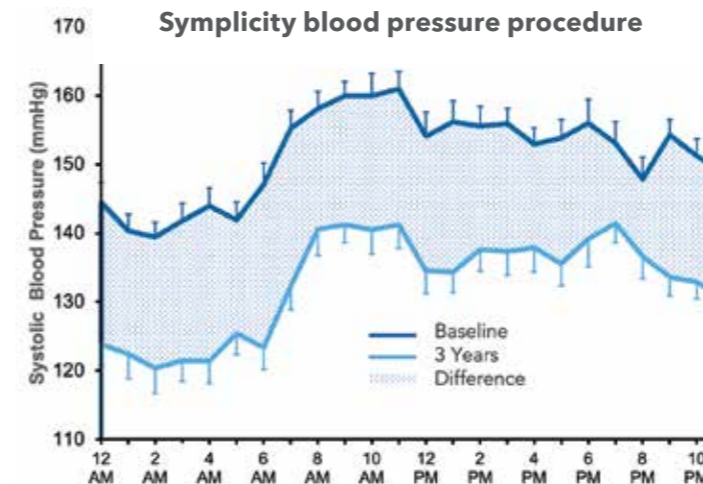
24-hour systolic blood pressure

-20.1 mmHg

office systolic blood pressure

>80%

of patients taking meds achieved SBP <140 mmHg with the Symplicity procedure



ALWAYS-ON blood pressure reduction

The Symplicity blood pressure procedure reduces blood pressure 24 hours a day, independent of patient behavior.

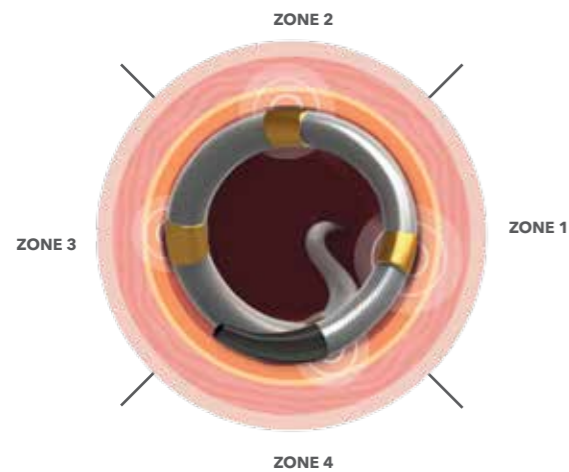
Excellent procedural and long-term safety

- Zero device or procedural safety events through three years
- Renal denervation did not negatively affect kidney function

Symlicity Spyrals™ multi-electrode renal denervation catheter

Performance
for simplicity
and versatility

One catheter size fits all eligible anatomy

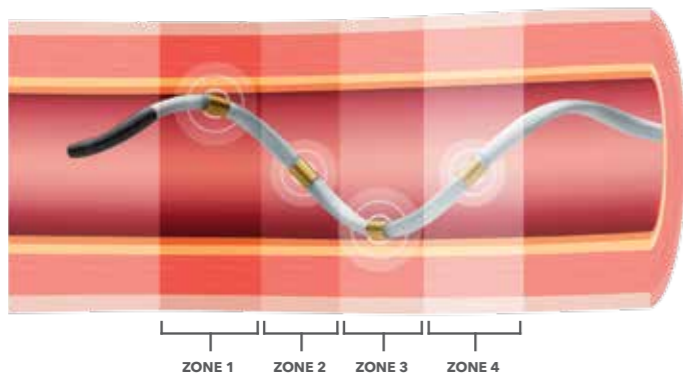


Single catheter treats a wide range of anatomy (vessels 3-8 mm in diameter)^{7,9}

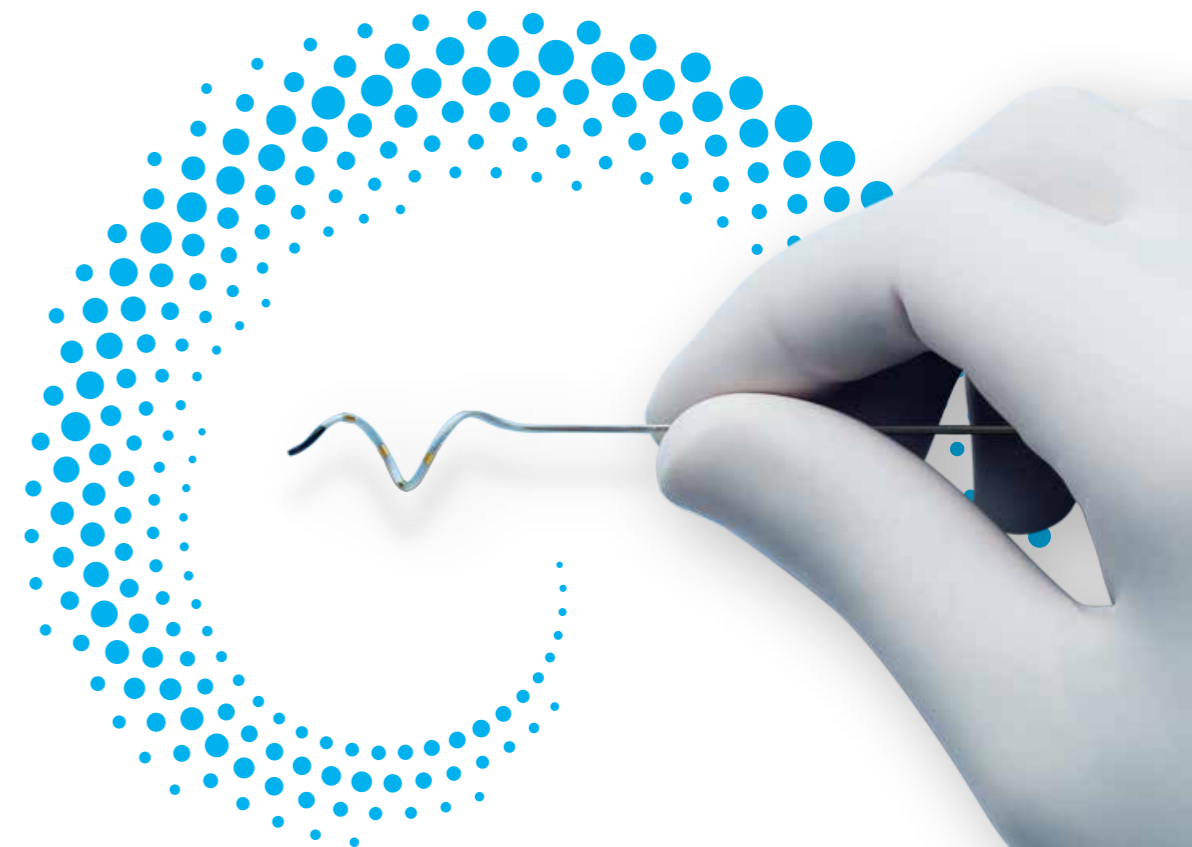
Utilizes a helical electrode pattern to ablate all four vessel quadrants simultaneously

Enables ablation of the main artery, accessory, and branch vessels to maximize the probability of complete denervation^{7,9}

Easy-to-use, rapid exchange, plug-and-play design



- Ability to navigate complex anatomy^{7,9}
- Non-occlusive catheter design allows for blood flow to naturally irrigate and cool the arterial wall⁷
- Distal self-expanding array of four electrodes is advanced to the treatment site by tracking over a 0.014" guidewire
- Compatible with 6Fr guiding catheter





Partner
with a leader

Symlicity G3™ renal denervation RF generator

- Real-time responsive algorithm controls and monitors the safe distribution of energy to target nerves⁷
- Power delivery to each electrode automatically adjusts depending on real-time temperature and impedance sensor feedback⁸
- Individual electrodes can be selected or deselected depending on the ability to make full contact with vessel wall



Enhance your hypertension treatment strategies



Best-in-class training and education



Industry-leading field and customer support teams



Ongoing technology enhancement and innovation



Access to therapy awareness and referral resources



Patient preference and awareness campaigns

Components

- Symplicity Spyr™ multi-electrode renal denervation catheter: single-use RDN catheter for use only with the Symplicity G3 generator
- Symplicity G3 renal denervation RF generator: reusable RF generator, power cable, remote control, and DVI-D output for use with the Symplicity Spyr™ catheter

Optional Accessories

- Mobile cart: used with the Symplicity G3™ generator

Ordering information

Catalog number
RDN016 - Symplicity Spyr™ catheter
RDN017 - Symplicity G3™ generator (supplied standard with remote control)
RDN019 - Cart for Symplicity G3™ generator
THNDR190S - Thunder™ guidewire
SB6RDND1K - Sherpa NX™ Balanced 6Fr 55-cm guide catheter with RDND1 curve
LA6IMAK - Launcher™ 6Fr 55-cm guide catheter with IMA curve
SB6IMAK - Sherpa NX™ Balanced 6Fr 55-cm guide catheter with IMA curve
Dispersive Electrode: A disposable dispersive electrode with a molded connector specified for adult use that complies with IEC 60601-2-2 is required.

References

† Includes Symplicity Spyr™ and Flex™ catheters.

‡ Death, stroke, end-stage renal disease, or MI.

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. *The Lancet*. 2020; Published online March 29, 2020.
2. 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.
3. Mahfoud F, Mancia G, Schmieder R, et al. Three-year safety and efficacy in the Global Symplicity Registry: Impact of antihypertensive medication burden on blood pressure reduction. Presented at PCR e-course 2020.
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. *The Lancet*. 2022; 399:1401-1410.
5. Jung O, Gechter JL, Wunder C, et al. Resistant hypertension? Assessment of adherence by toxicological urine analysis. *Hypertension*. April 2013;31(4):766-774.
6. World Health Organization. Hypertension fact sheet. 25 August 2021. <https://www.who.int/news-room/fact-sheets/detail/hypertension>. Accessed November 3, 2021.
7. Coates P, Tunev S, Trudel J, et al. Time, temperature, power, and impedance considerations for radiofrequency catheter renal denervation. *Cardiovascular Revascularization Medicine*, 2022.
8. Medtronic Data on File.
9. Medtronic Symplicity Spyr™ Instructions for Use.

Medtronic

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See the device manual for information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu.

For distribution only in markets where the Symplicity Spyr™ multi-electrode renal denervation catheter and Symplicity G3™ renal denervation RF generator have been approved. Not for distribution in the USA, Japan or France.