Medtronic

Symplicity Spyral™
renal denervation system

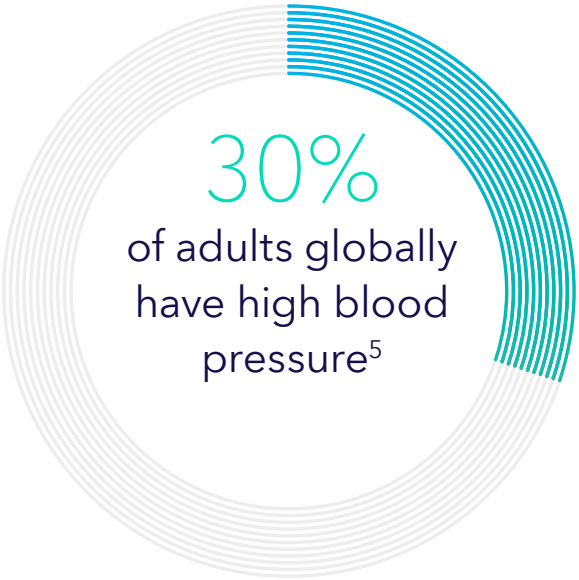
Setting the standard

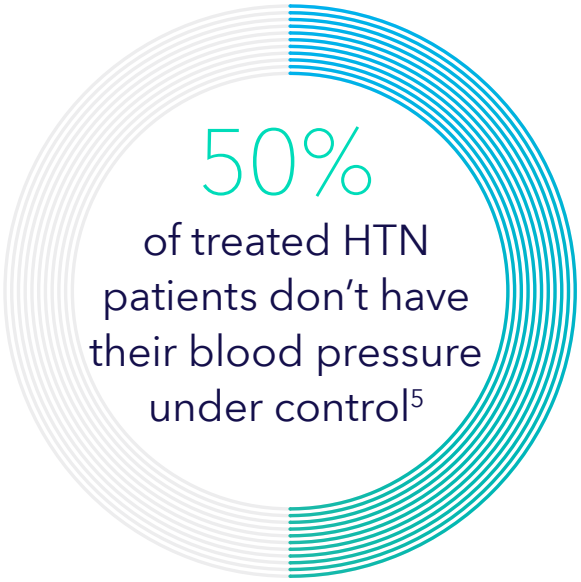
in renal denervation

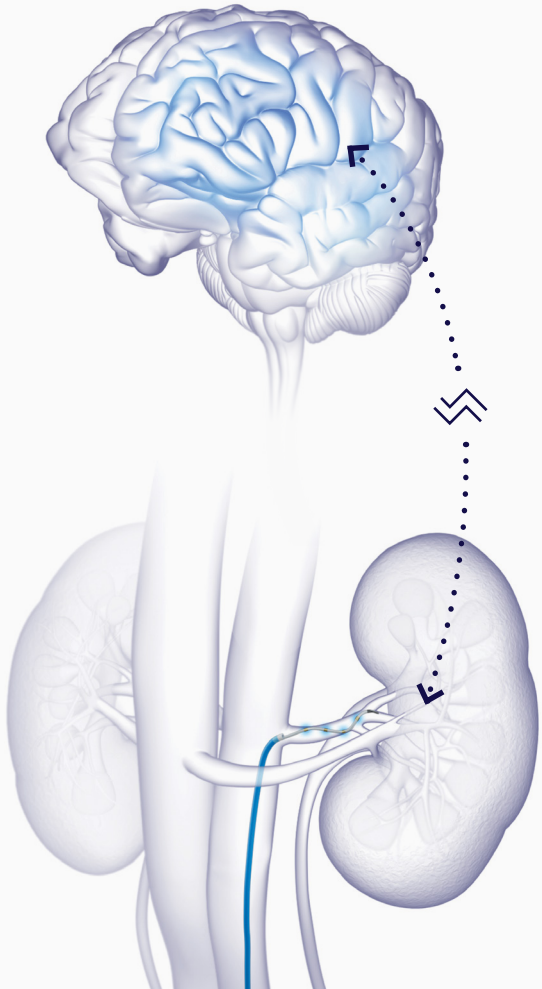
The Symplicity™ blood pressure procedure delivers significant, safe, and sustained BP reductions.[1-4]

When typical hypertension treatments aren't enough

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







How renal denervation with Symplicity Spyral works:

- The kidneys modulate the sympathetic tone via the renal nerves to control blood pressure
- Symplicity Spyral supplies precisely controlled and targeted radiofrequency energy to the renal nerves[6]
- The procedure safely disrupts the overactive sympathetic signaling between the kidneys and brain, to reduce blood pressure[6]

Turn to an approach recommended by societies

2024 European Society of Cardiology (ESC) Guidelines and 2023 European Society of Hypertension (ESH) Guidelines now recommend renal denervation as a safe and effective treatment option in uncontrolled and resistant hypertension[7,8].

European Guidelines: Patient selection criteria[7,8]

Uncontrolled BP

Patients who have **uncontrolled hypertension** with eGFR >40 ml/min/1.73m^2 on fewer than 3 antihypertensive drugs with increased CV Risk

Resistant Hypertension

Patients with resistant hypertension with eGFR >40 ml/min/1.73m^2 who have uncontrolled BP despite a 3-drug combination*

* Including a thiazide or thiazide-like diuretic

Additional recommendations[7,8]

Selection of patients should be done in a **shared decision-making process** taking into account **patient preference**

Renal denervation should be performed in experienced RDN centers after a **multidisciplinary assessment****

** A multidisciplinary team is defined as two or more healthcare professionals working together. This can include, but is not limited to, a proceduralist and a non-invasive physician.

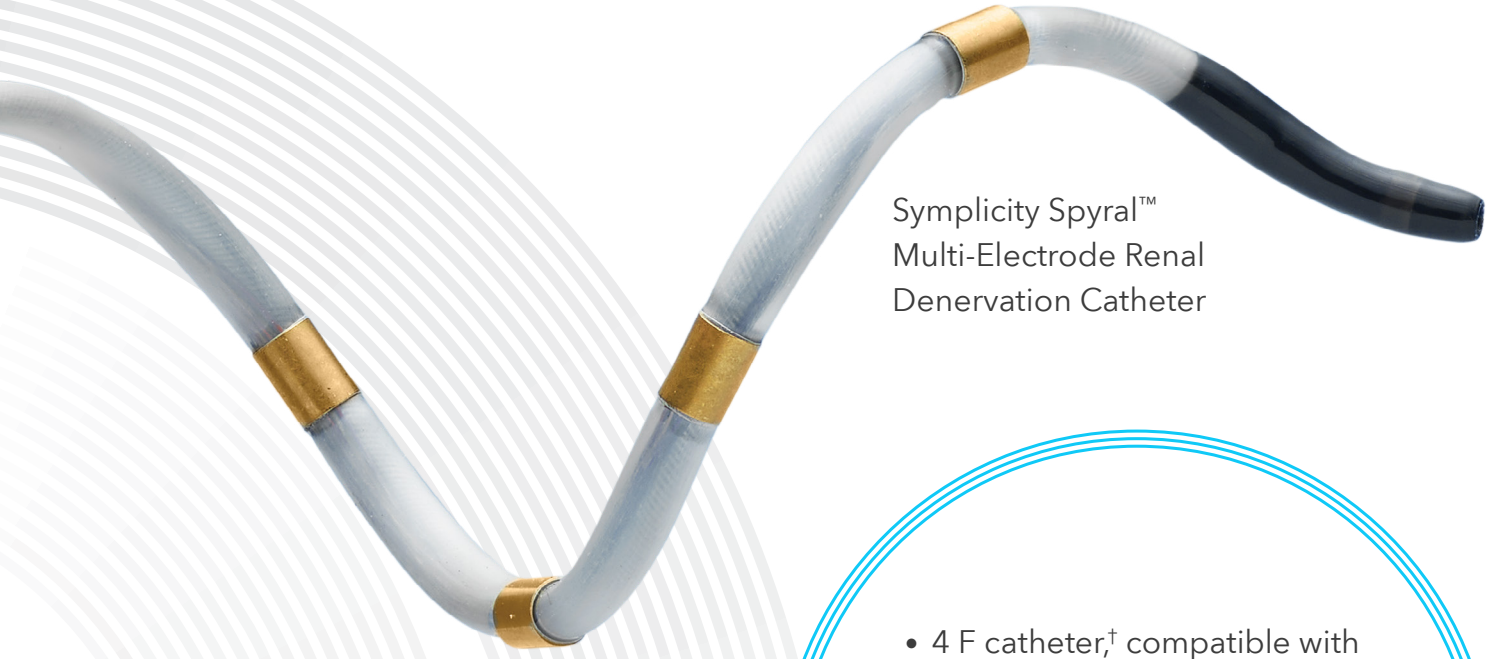
Based on definitions, ESC classification IIb and ESH classification I vary slightly on shared decision making and experienced centers.

Setting the standard in renal denervation

Most used RDN system[9]

>30,000 patients treated globally with the Symplicity RDN system[9]

The Symplicity™ blood pressure procedure is a simple, minimally-invasive approach to achieve BP reductions, independent of patient adherence. Precisely controlled and targeted **radiofrequency (RF) energy** is delivered to the renal nerves[6] with no permanent implant left behind.

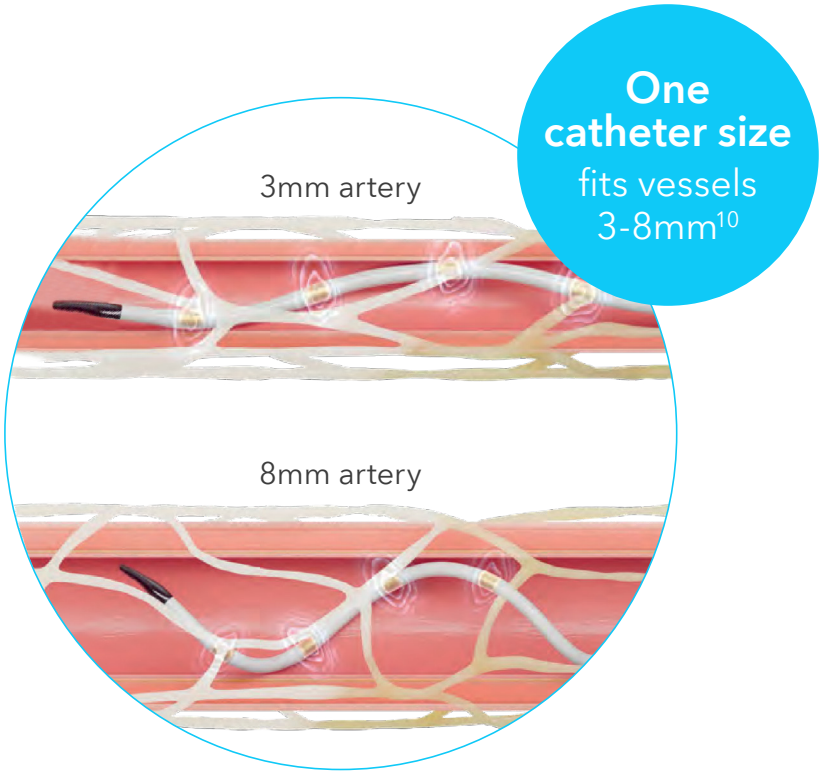


Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter

- 4 F catheter,† compatible with 6 F guide catheter, 0.014" guidewire
- Four independently controlled electrodes
- Shaped atraumatic tip with radiopaque marker

Simple and versatile

- One catheter size fits vessels 3-8mm[10]
- Easy-to-use, **plug-and-play** design
- **Nonocclusive design** allows for continuous blood flow to naturally protect the vessel wall[6]



Safe and precise

Safe

- Radiofrequency energy preferentially heats fat tissue where renal nerves are located and **avoids non-target structures**[11]
- Unique, real-time and **responsive algorithm** automatically adjusts power by monitoring temperature and impedance for safe energy distribution[6]

Precise ablation

- Multi-electrode, helical design covers four quadrants simultaneously for a circumferential ablation[6,10]
- Symplicity Spyral™ 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]

Symplicity G3™ Renal Denervation RF Generator

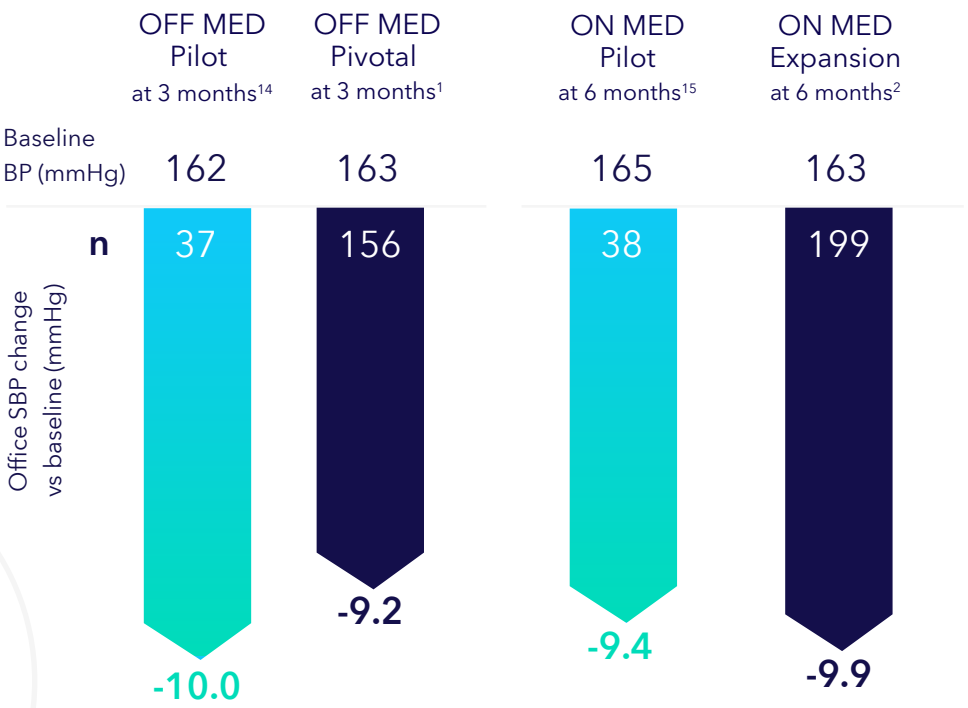
Significant, safe, and sustained blood pressure reductions[1-4]

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

>5,000 patients enrolled in the global clinical program[‡18]

Significant

Consistent blood pressure reductions in 4 sham-controlled trials, in both the presence and absence of medications [1,2,14,15]



9 mmHg

OSBP reduction in patients off and on medications[1,2,14,15]

Safe

Excellent safety profile[1,2]

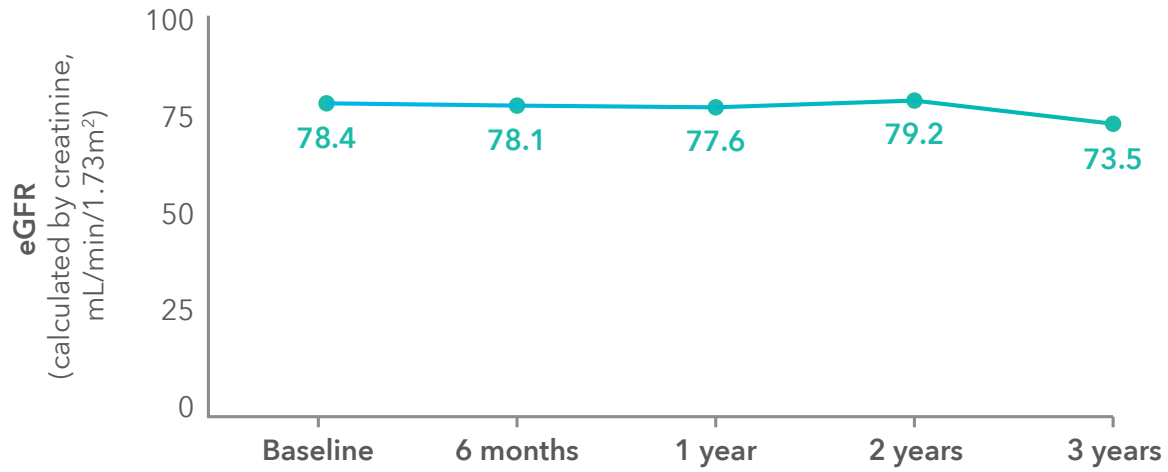
Pooled data indicated low incidence of procedural and clinical adverse events[2]

Stable kidney function

Minimal impact to kidney function at 3-year follow-up[16]

0.4%

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



Sustained

Confidence in durable, real-world outcomes with Symplicity™ system, demonstrating lasting blood pressure reductions **at 3 years** in over 1,300 real-world patients.[17]

17

mmHg

reduction in OSBP at 3 years. n=1337[17]

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)
Guidewire: 0.014" non-hydrophilic guidewire with a supportive shaft and a floppy tip
Guide catheter: 6 F guide catheter (90 cm max length) Recommended models: **SB6RDND1K** – Sherpa NX™ Balanced 6Fr 55-cm guide catheter with RDND1 curve **LA6RDCK** - Launcher™ 6Fr 55-cm guide catheter with RDC 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 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.

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[2] Kandzari DE, Townsend RR, Kario K, at al. Safety and Efficacy of Renal Denervation in Patients Taking Antihypertensive Medications. J Am Coll Cardiol. 2023 ;82(19) :1809-1823
[3] Mahfoud F, Mancia G, Schmieder RE, et al. Outcomes Following Radiofrequency Renal Denervation According to Antihypertensive Medications: Subgroup Analysis of the Global SYMPLICITY Registry DEFINE. Hypertension. 2023;80(8):1759-1770
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[8] McEvoy et al. European Heart Journal 2024 Oct 7;45(38):3912-4018. doi: 10.1093/eurheartj/ehae178
[9] Medtronic Data on File, RDN Catheter Historic Data, Feb 2025. 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, Maranillo 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.
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[17] Mahfoud F, et al. Outcomes following radiofrequency renal denervation according to antihyptensive medications: subgroup analysis of the Global SYMPLICITY Registry DEFINE. EuroPCR 2023. Data inlcudes both Symplicity Flex and Symplicity Spyral.
[18] Medtronic data on file, Patients in clinical program, Feb 2025. Data includes both Symplicity Flex and Symplicity Spyral.

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Learn more on renal denervation

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