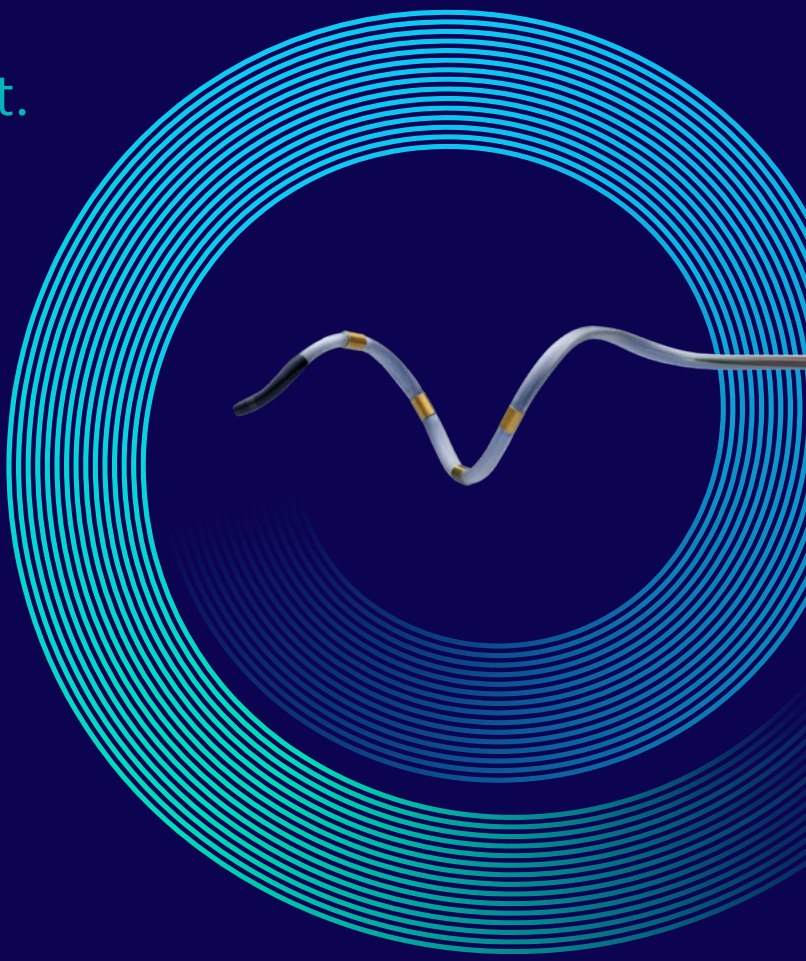
Medtronic

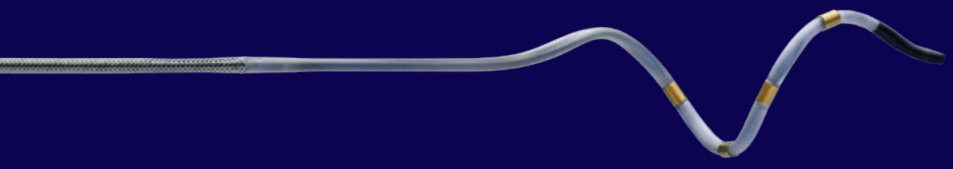
Symplicity Spyral™
renal denervation (RDN) system

Get more with the Symplicity Spyral RDN system

More clinical experience.
More optimized treatment.
More confidence.



Optimize denervation with the Symplicity Spyral RDN catheter



	MEDTRONIC SYMPLICITY SPYRAL RDN SYSTEM	VS. RECOR PARADISE™* RDN SYSTEM
KEY DESIGN ELEMENTS		
Single catheter design that fits more vessels and bypasses extra decision making to optimize procedure time	**One catheter** fits vessels 3–8 mm[1] 3.00 LMA/RMA diameter (mm) 8.00	Six balloon sizes[2] 3.00 LMA/RMA diameter (mm) 8.00 3.5 mm for 3 to < 3.5 mm vessels 4.2 mm for 3.5 to < 4.2 mm vessels 5 mm for 4.2 to < 5 mm vessels 6 mm for 5 to < 6 mm vessels 7 mm for 6 to < 7 mm vessels 8 mm for 7 to ≤ 8 mm vessels
Low-profile catheter design reduces access site complications[3]	**4 F** RX catheter w/6 F guide†	**6 F** OTW catheter w/7 F guide[2,4]
CLINICAL EXPERIENCE		
One device to treat the largest variety of anatomies	**3% anatomical exclusions**[5,6] (8x less vs. Recor) in RCTs after adjusting for BP screen outs	**26% anatomical exclusions**[7–9] in RCTs after adjusting for BP screen outs
Studies that investigated the largest number of patients	**4,119 (6x vs. Recor)**[5,6,10–12] Total number of patients in the program **1,907 (19x vs. Recor)**[10,14–18] Number of patients at 3 years	**625**[7–9,13] Total number of patients in the program **100**[19,20] Number of patients at 3 years

RX = rapid exchange
OTW = over-the-wire
RCT = randomized controlled trial

More clinical experience

With over 4,000 patients enrolled in the SPYRAL HTN Clinical Program, **Symplicity Spyral RDN system has the most evidence** to better inform clinical practice.[‡,§,4,5,9]

Patients studied

4,119
SPYRAL HTN Clinical Program[‡,5,6,10-12]

625
RADIANCE™* Global Program[7-9,13]

Patients at 3 years

1,907
SPYRAL HTN Clinical Program[10,14-18]

100
RADIANCE™* Global Program[19,20]

Procedural experience in randomized controlled trials[¶]

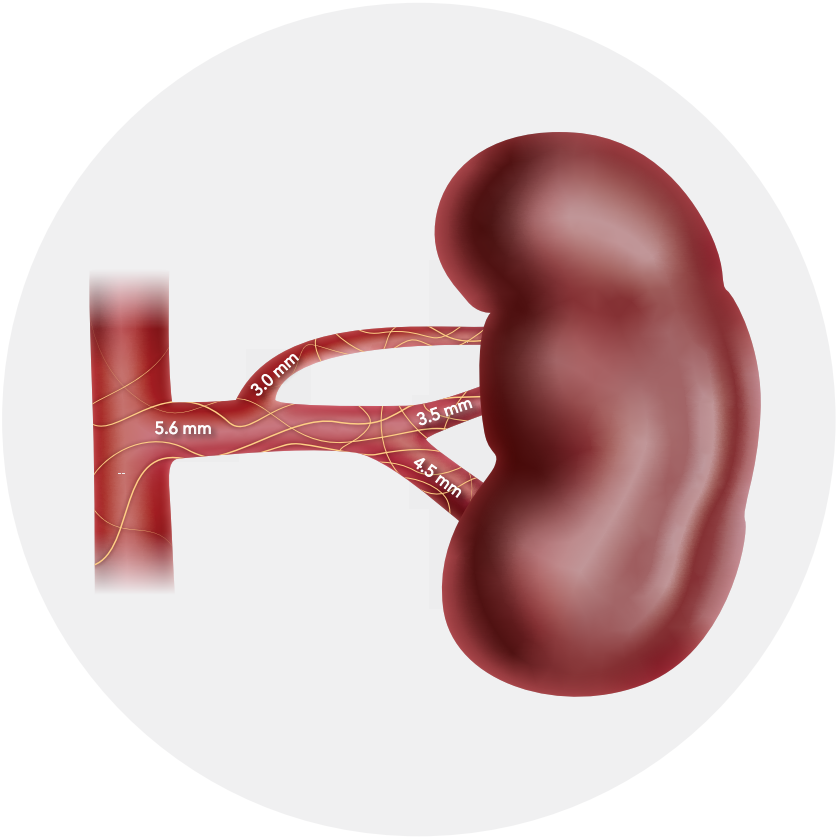
97%
patients treated
with Symplicity Spyral RDN system[5,6]
(**53 anatomical exclusions** of 1,591 patients)[5,6]

26%
patients were not treated
with the Paradise RDN system due to anatomical exclusions[7-9]
(**404 anatomical exclusions** of 1,534 patients)[7-9]

¶ After adjusting for blood pressure screen outs.

Optimized treatment in more patients

Renal anatomy can be complex. Only the Symplicity Spyral RDN system can deliver therapy throughout all eligible vessels with a single catheter – including the distal main and branches where the nerves are nearest to the vessel **– allowing you to treat even more patients.**[#,1,2]

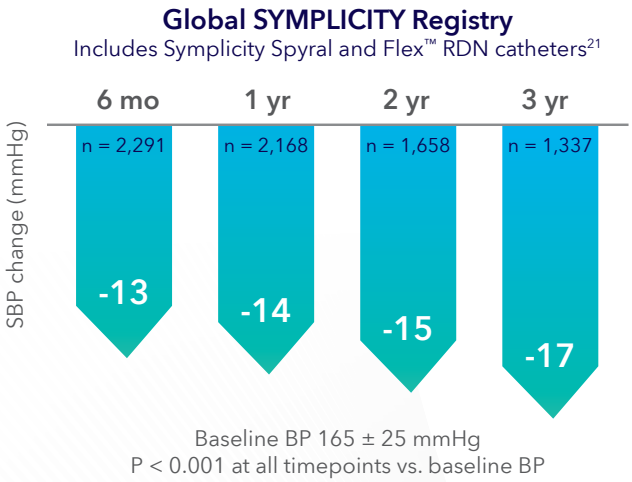


	MEDTRONIC SYMPLICITY SPYRAL RDN SYSTEM[1]	VS.	RECOR PARADISE RDN SYSTEM[2]
TREATMENT TARGET	**Maximize renal denervation potential** by treating all eligible vessels sized 3–8 mm, including main, accessories, and branches.		Target 2–3 sonications in eligible vessels sized 3–8 mm, including main, accessories, and proximal branches.
ANATOMICAL CONSIDERATIONS FOR ELIGIBLE VESSELS **Renal artery diameter**	**One catheter** treats vessels 3–8 mm		Choose 1 of 6 catheters based on the smallest artery diameter at each treatment location. Failure to use the recommended balloon size may result in renal artery injury, ablation of unintended targets, and/or unsuccessful ablation of target tissue.
Minimum artery length	**N/A** If an electrode is not located within the renal artery, or if any electrode deploys in an unsuitable location, individual electrodes can be turned off, allowing treatment to still be delivered through the other electrodes.		Vessel must accommodate balloon length and allow placement at least 5 mm from both the ostium and the kidney parenchyma while avoiding branchpoints and bifurcation.
Adjacent vessels	**N/A**		Emission zones should not overlap between adjacent vessels. To avoid overlapping treatment zones, a minimum 10 mm must be maintained between vessels or sonications must be staggered.

More confidence in durable, real-world outcomes

With the Symplicity RDN system, you can be confident you are treating the most nerves possible with a catheter **proven to deliver durable results at 3 years in over 1,300 real-world patients,** maximizing the potential for positive patient outcomes.[‡,◊,10]

Durable results in real-world patients[‡,◊,21]



Real-world patients

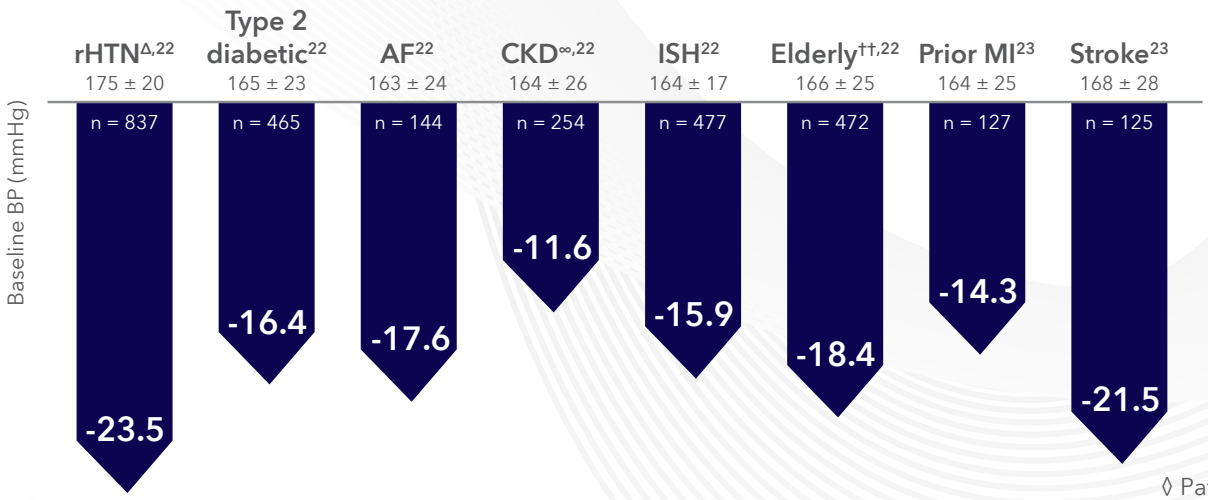
Global SYMPLICITY Registry

3,700

Global Paradise System Registry

No published data
as of June 2024.
Now enrolling.

Blood pressure reductions in high-risk patient subgroups at 3 years[‡]



◊ Patient results may vary.

™*Third-party brands are trademarks of their respective owners.
† Catheter dimension of 0.052" is average maximum diameter determined during design verification. Upper bound allowable is 0.061".
‡ Includes Symplicity Spyral and Flex catheters.
§ Study follow-up is ongoing. Data does not represent follow-up for all patients.
◊ Patient results may vary.
¶ After adjusting for blood pressure screen outs.
# May not be indicative of clinical performance.
Δ Resistant hypertension defined as OSBP > 150 mmHg, ≥ 3 antihypertensive medications.
∞ CKD defined as eGFR < 60 mL/min/1.73m^2.
†† Elderly defined as 65 years or older.

1. Medtronic Symplicity Spyral multi-electrode renal denervation catheter Instructions for Use.
2. Recor Paradise Ultrasound Renal Denervation System Instructions for Use.
3. Cantor WJ, et al. *Catheter Cardiovasc Interv.* 2007;69:73–83.
4. Devireddy C. How to Perform Ultrasound-based Renal Denervation (uRDN). October 2023. TCT, San Francisco.
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7. Azizi M, et al. *Lancet.* 2018;391:2335–2345.
8. Azizi M, et al. *JAMA.* 2023;329:651–661.
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12. Kandzari DE, et al. *Lancet.* 2018;391:2346–2355.
13. Kario K, et al. *Hypertens Res.* 2022;45:221–231.
14. Krum K, et al. *Lancet.* 2014;383: 622–629.
15. Mahfoud F, et al. *Lancet.* 2022;399:1401–1410.
16. Esler MD, et al. *Eur Heart J.* 2014;35:1752–1759.
17. Bhatt DL, et al. *Lancet.* 2022; 400:1405–1416.
18. Kario K, et al. *Circ J.* 2019;83:622–629.
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21. Mahfoud F, et al. Outcomes following radiofrequency renal denervation according to antihypertensive medications: subgroup analysis of the Global SYMPLICITY Registry DEFINE. EuroPCR 2023.
22. Mahfoud F, et al. *J Am Coll Cardiol.* 2020;75:2879–2888.
23. Mahfoud, F, et al. Blood pressure reduction after catheter-based renal denervation in patients with cardiovascular disease in the Global SYMPLICITY Registry. ESH 2022.

Indications
The Symplicity Spyral™ renal denervation system is indicated to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure.

Contraindications
The Symplicity Spyral system is contraindicated in patients with any of the following conditions: • Renal artery diameter < 3 mm or > 8 mm • Renal artery fibromuscular dysplasia (FMD) • Stented renal artery (< 3 months prior to RDN procedure) • Renal artery aneurysm • Renal artery diameter stenosis > 50% • Pregnancy • Presence of abnormal kidney (or secreting adrenal) tumor • Iliac/femoral artery stenosis precluding insertion of the catheter.

Warnings and Precautions
A thorough understanding of the technical principles, clinical applications, and risks associated with vascular access techniques and percutaneous transluminal catheterization in renal arteries is necessary before using this device.

The safety and efficacy of the Symplicity Spyral system has not been established in patients with isolated systolic hypertension or in patients with prior renal artery interventions including renal stents, renal angioplasty, or prior renal denervation. The Symplicity Spyral system has not yet been studied in patients who are breastfeeding, under the age of 18, or with secondary hypertension. • Avoid treatment with the Symplicity Spyral™ catheter within 5 mm of any diseased area or stent. • Implantable pacemakers (IPGs) and implantable cardioverter defibrillators (ICDs) or other active implants may be adversely affected by RF ablation. Refer to the implantable device's *Instructions for Use*. • The patient's heart rate may drop during the ablation procedure. • Proper pain medication should be administered at least 10 min before ablating renal nerves.

Adverse events include, but are not limited to, pain and hematoma. Results may vary.

Potential Adverse Events
Potential adverse events associated with use of the renal denervation device or the interventional procedures include, but are not limited to, the following conditions: • Allergic reaction to contrast • Arterial damage, including injury from energy application, dissection, or perforation • Arterial spasm or stenosis • Arterio-enteric fistula • AV fistula • Bleeding • Blood clots or embolism • Bruising • Cardiopulmonary arrest • Complications associated with medications commonly utilized during the procedure, such as narcotics, anxiolytics, or other pain or anti-vasospasm medications • Death • Deep vein thrombosis • Edema • Electrolyte imbalance • Heart rhythm disturbances, including bradycardia • Hematoma • Hematoma – retroperitoneal • Hematuria • Hypertension • Hypotension (may cause end organ hypoperfusion) • Infection • Kidney damage including renal failure or perforation • Myocardial infarction • Nausea or vomiting • Pain or discomfort • Peripheral ischemia • Pulmonary embolism • Proteinuria • Pseudoaneurysm • Radiocontrast nephropathy • Renal artery aneurysm • Skin burns from failure of the dispersive electrode pad • Stroke • Other potential adverse events that are unforeseen at this time.

Please reference appropriate product *Instructions for Use* and *User Manual* for more information regarding indications, contraindications, warnings, precautions, and potential adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

For further information, please call and/or consult Medtronic at 800-633-8766 or the Medtronic website at medtronic.com.

Medtronic

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For U.S. healthcare professionals: **medtronic.com/SymplicityProcedure**
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