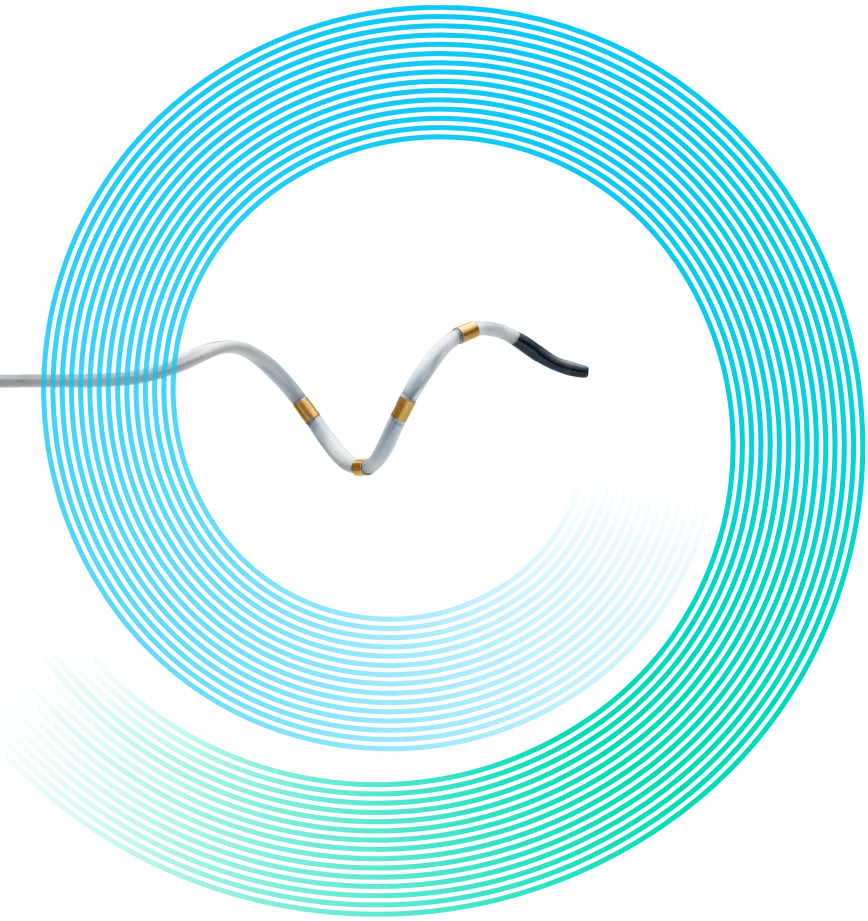
Medtronic

Symplicity Spyral™
multi-electrode renal denervation catheter

One catheter size, easy-to-use design

The Symplicity Spyral™ multi-electrode RDN catheter offers an easy-to-use, plug-and-play design. One catheter size fits vessels 3–8 mm in diameter, enabling access to the main renal artery, accessory, and branch vessels during the Symplicity™ blood pressure procedure. The multi-electrode, helical design covers four quadrants simultaneously for a circumferential ablation to maximize the probability of a complete denervation.[1,2]



Proven to deliver significant, safe, and sustained blood pressure reductions†[3-6]

As part of the Symplicity Spyral™ renal denervation system, the Symplicity Spyral catheter supplies precisely controlled and targeted radiofrequency (RF) energy to the renal nerves to safely disrupt overactive sympathetic signaling between the kidneys and brain.[1]

- Distal self-expanding array of four electrodes
- Tracks over a 0.014″ guidewire
- Unique electrode pattern separates ablation zones and preserves vascular function
- Non-occlusive catheter design allows for continuous blood flow to protect the vessel wall[1]

Components

- Catheter: 4F catheter,‡ compatible with 6F guide catheter, 0.014″ guidewire
- Electrodes: 4 RF monopolar, gold, radiopaque, 1.5 mm length
- Tip marker: platinum/iridium alloy
- Handle: injection molded
- Integrated extension cable for connection with the Symplicity G3™ renal denervation RF generator

Materials

Handle

ABS, thermoplastic elastomer overmold

Thermocouple

T-type

Catheter – RDN016

- Proximal shaft: polyether block amide laminated over stainless steel
- Intermediate tubing: polyether block amide with braided stainless steel
- Distal electrode array jacket: thermoplastic urethane
- Tip: thermoplastic
- Guidewire lumen: high-density polyethylene liner
- Spiral shaping element: nickel/titanium
- Guidewire loading tool: thermoplastic

Not present

- Latex
- Phthalate

Technical Specs

- Rapid exchange design
- Guidewire retraction used to deploy the spiral electrode array
- RX joint: 30 cm from distal tip
- Vessel diameter treatment range: 3–8 mm
- Four independently controlled RF monopolar gold electrodes, spaced ~6.5 mm apart
- Treatment length: 17–21 mm if all electrodes are activated
- Tip length: ~5 mm
- Tip marker: 1 mm proximal of distal tip
- Femoral shaft marker: 55 cm from distal tip

Size

- 117 cm working length-compatible with 90 cm or shorter guide catheters
- 55 cm length is recommended; 90 cm max length
- 0.052" OD‡

Sterilization process

E-beam and 10-6 SAL

Shelf life

Three years

Refer to the Instructions for Use (IFU) and User Manual for full product information.

†Results may vary.

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

[1] Coates P, Tunev S, Trudel J, Hettrick DA. Time, Temperature, Power, and Impedance Considerations for Radiofrequency Catheter Renal Denervation. *Cardiovasc Revasc Med*. September 2022;42:171-177.

[2] Medtronic Symplicity Spyral™ Instructions for Use.

[3] 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(10333):1444-1451.

[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. Lancet. April 9, 2022;399(10234):1401–1410.

[5] Mahfoud F, et al. Outcomes following radiofrequency renal denervation according to antihypertensive medications: subgroup analysis of the Global SYMPLICITY Registry DEFINE. EuroPCR 2023.

[6] Kandzari DE, Townsend RR, Kario K, et al. Safety and Efficacy of Renal Denervation in Patients Taking Antihypertensive Medications. *J Am Coll Cardiol*. November 7, 2023;82(19):1809–1823.

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.

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 707-525-0111 or Medtronic's website at medtronic.com.

Medtronic.com/SymplicityProcedure

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