

Symplicity Spyral™ multi-electrode renal denervation catheter

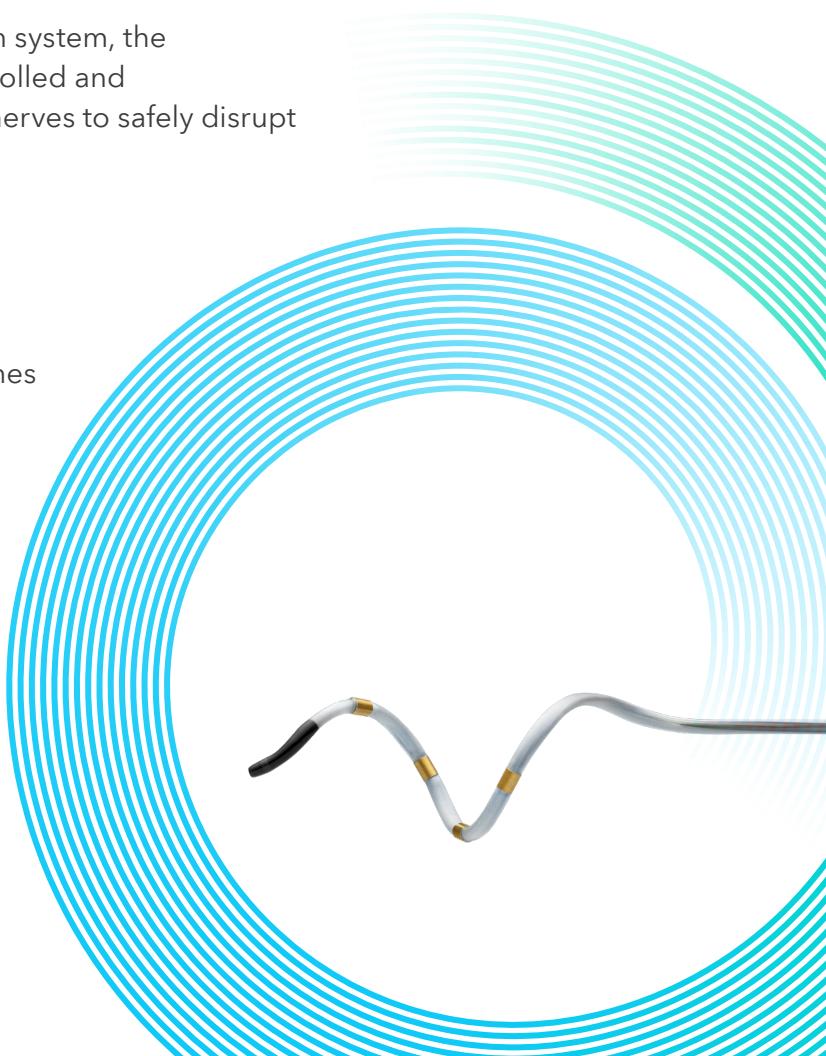
One catheter size, easy-to-use design

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 allows for ablation in four quadrants simultaneously to maximize the probability of a complete denervation.^{1,2}

Proven to deliver significant, safe, and sustained blood pressure reductions³⁻⁷

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 wall¹



Components



- Catheter: 4F catheter[†], compatible with 6F guide catheter, 0.014" guidewire
- Electrodes: 4 RF monopolar, gold, radio-opaque, 1.5 mm length
- Thermocouple: T-type
- 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

- 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

Size

- working lenght: 117 cm. Compatible guide catheter max length: 90 cm (55 cm length recommended)
- maximum OD: 0.052"

Technical Specs

- Rapid exchange design compatible with 0.014" guidewire
- 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

Sterilisation process

E-beam and 10⁻⁶ SAL

Shelf life

Three years

[†] Catheter dimension of 0.052" is average diameter determined during design verification. Upper bound allowable is 0.061".

¹ Coates P, Tuney 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(10234):1444-1451.

⁴ Kandzari DE, Townsend RR, Kario K, et al. Safety and Efficacy of Renal Denervation in Patients Taking Antihypertensive Medications. *J Am Coll Cardiol*. 2023;82(19):1809-1823.

⁵ 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*. 2022;399(10333):1401-1410.

⁶ Mahfoud F, EuroPCR 2023.

⁷ Mahfoud F, Mancia G, Schmieder RE, et al. Outcomes Following Radiofrequency Renal Denervation According to Antihypertensive Medications: Subgroup Analysis of the Global SYMPPLICITY Registry DEFINE. *Hypertension*. 2023;80(8):1759-1770

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

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