



Symlicity Spyral™

multi-electrode renal denervation catheter

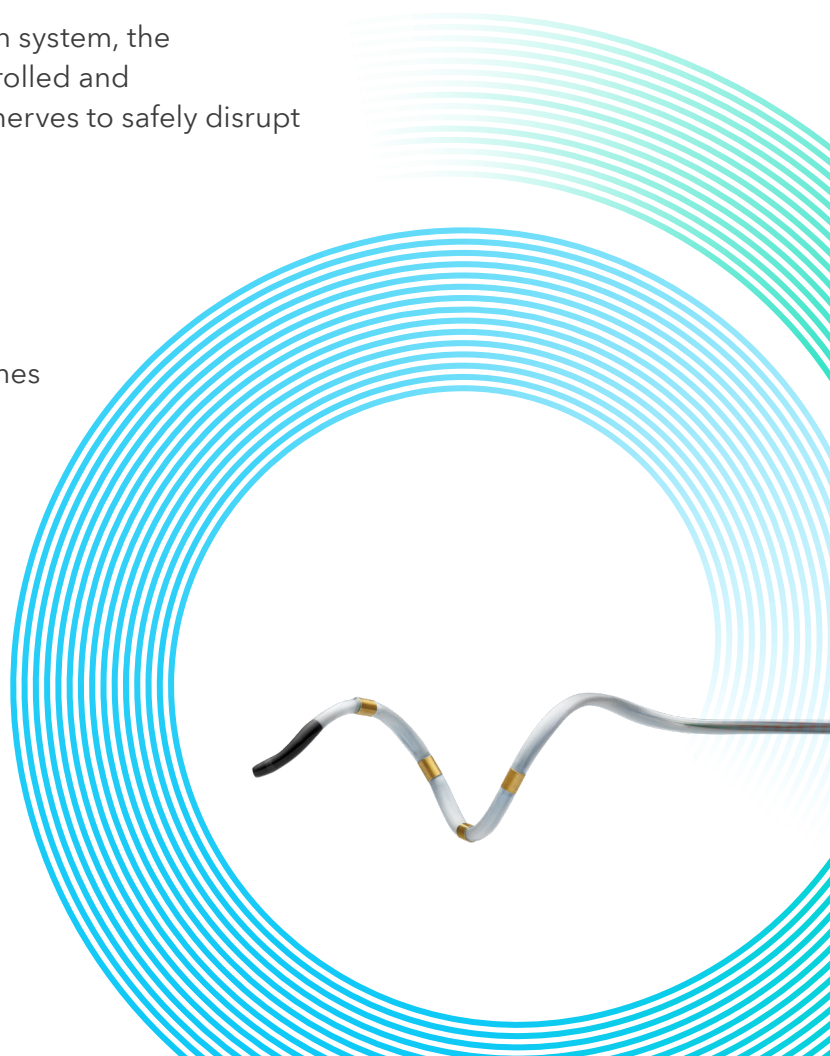
One catheter size, easy-to-use design

The Symlicity 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 Symlicity™ 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 Symlicity Spyral™ renal denervation system, the Symlicity 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 length: 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



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

[†] Catheter dimension of 0.052" is average 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 Spyr™ 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

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.