

Medtronic

Engineering the extraordinary

Symlicity Spyral™ Multi-Electrode Renal Denervation Catheter

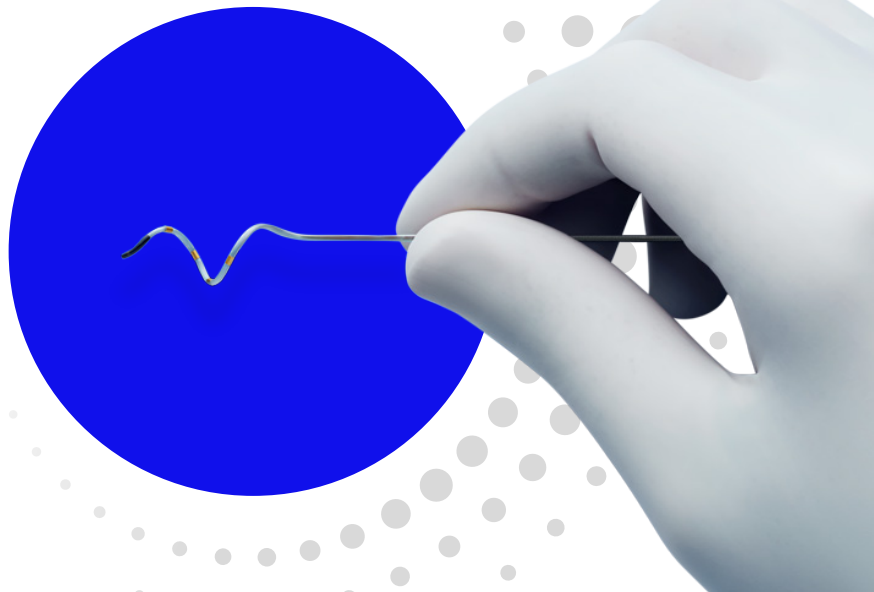
Single catheter, easy-to-use design

The Symlicity Spyral™ multi-electrode RDN catheter offers an easy-to-use, rapid exchange, plug-and-play design. It has the ability to treat a wide range of anatomy (vessels 3-8 mm in diameter), enabling ablation of the main artery, accessory, and branch vessels to maximize the probability of complete denervation^{1,2} during the Symlicity™ blood pressure procedure.

Significant, safe, and sustained blood pressure reductions³⁻⁵

As part of the Symlicity Spyral™ renal denervation system, the Symlicity Spyral catheter supplies precisely controlled and targeted radiofrequency (RF) energy to the renal nerves¹ 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
- Deploys in a helical pattern to ablate all four vessel quadrants simultaneously
- Unique electrode pattern separates ablation zones and preserves vascular function
- Non-occlusive design allows for blood flow to naturally irrigate and cool the arterial wall¹



Components



- Catheter: 6Fr guide catheter-compatible
- 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

- 117-cm working length-compatible with 90 cm or shorter guide catheters
- 6Fr guide catheter-compatible
- 0.052" maximum OD

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

3 years

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

1. Coates P, Tunev S, Trudel J, et al. Time, temperature, power, and impedance considerations for radiofrequency catheter renal denervation. *Cardiovascular Revascularization Medicine*, 2022.
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. *The Lancet*. 2020; Published online March 29, 2020.
4. Kandzari DE, Böhm M, Mahfoud F, et al. Effect of renal denervation on blood pressure in the presence of antihypertensive drugs: 6-month efficacy and safety results from the SPYRAL HTN-ON MED proof-of-concept randomised trial. *The Lancet*. 2018 Jun 9;391(10137):2346-2355.
5. Mahfoud F, Mancia G, Schmieder R, et al. Three-year safety and efficacy in the Global Symplicity Registry: Impact of antihypertensive medication burden on blood pressure reduction. Presented at PCR e-course 2020.

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