Medtronic

Symplicity Spyral™

multi electrode renal denervation system

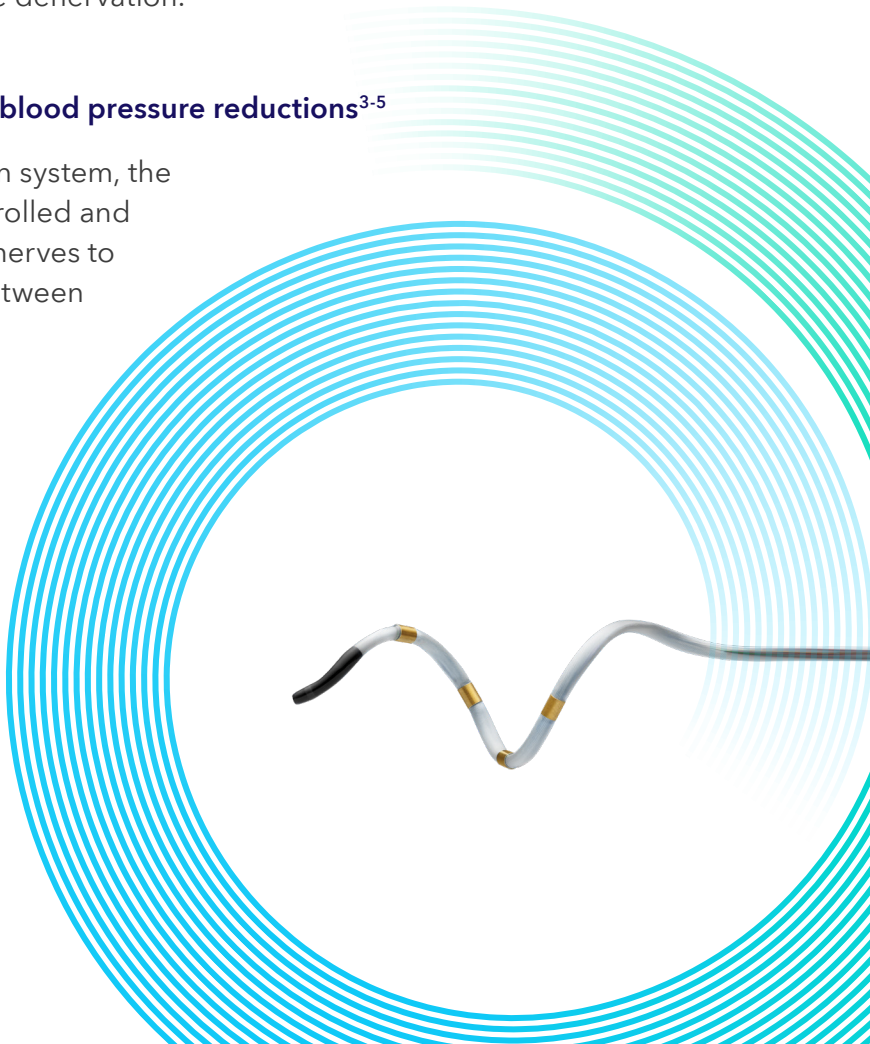
One catheter size, easy-to-use design

The Symplicity Spyral™ multi-electrode renal denervation 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[3-5]

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, 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 – 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

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†

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 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(10234):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, 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.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

medtronic.ca

©2024 Medtronic. All rights reserved. Medtronic, Medtronic logo and Engineering the extraordinary are trademarks of Medtronic. ™*Third party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic company.

UC202404491EC CA-CTL-0315-E Rev. 03/2024

Medtronic