

Medtronic

Engineering the extraordinary

Symlicity Spyral™ Multi-Electrode Renal Denervation Catheter

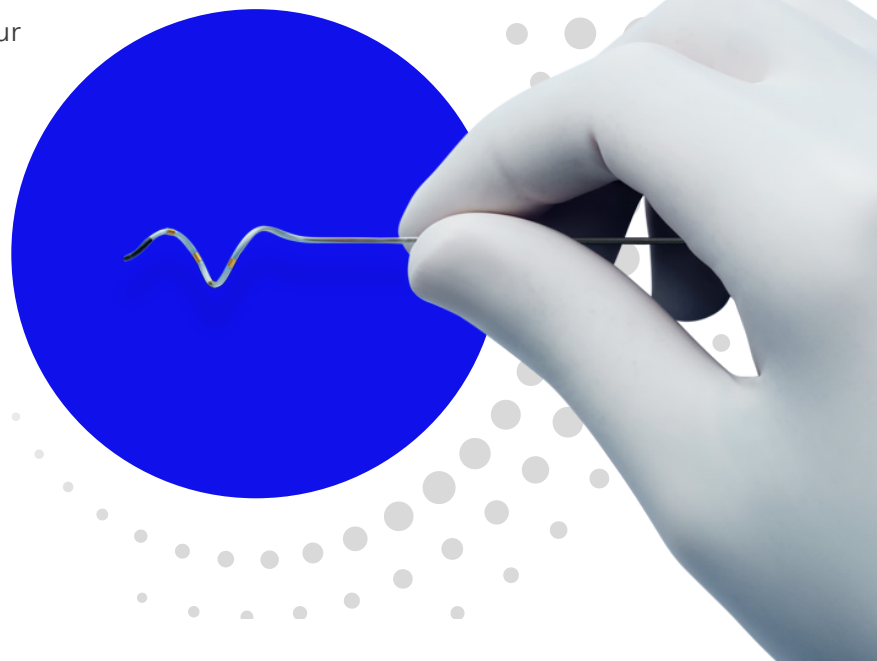
Single catheter, easy-to-use design

The Symlicity Spyral™ multi-electrode RDN catheter offers an easy-to-use, rapid exchange, plug-and-play design. It has the deliverability 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 denervation¹⁻³ during the Symlicity™ blood pressure procedure.

Significant, safe, and sustained blood pressure reductions^{1,4-7}

As part of the Symlicity™ Renal Denervation System, the Symlicity Spyral catheter delivers precisely controlled and targeted radiofrequency (RF) energy to the renal nerves to safely disrupt overactive sympathetic signaling between the kidneys and brain.

- 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 arterial wall



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. Townsend RR, Mahfoud F, Kandzari DE, et al. Catheter-based renal denervation in patients with uncontrolled hypertension in the absence of antihypertensive medications (SPYRAL HTN-OFF MED): a randomised, sham-controlled, proof-of-concept trial. *The Lancet*. 2017;390:2160-2170.
2. Whitbourn B, Harding SA, Walton A. Symplicity multi electrode radiofrequency renal denervation feasibility study. *Eurointervention*. 2015; 11:104-9.
3. Medtronic Symplicity Spyral™ Instructions for Use.
4. 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.
5. 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.
6. As of August 2018, Medtronic safety data on file.
7. 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.

Medtronic

Europe

Medtronic International Trading Sàrl.
Route du Molliau 31
Case postale
CH-1131 Tolochenaz
www.medtronic.eu
Tel: +41 (0)21 802 70 00
Fax: +41 (0)21 802 79 00

United Kingdom/Ireland

Medtronic Limited
Building 9
Croxley Park
Hatters Lane
Watford
Herts WD18 8WW
www.medtronic.co.uk
Tel: +44 (0)1923 212213
Fax: +44 (0)1923 241004

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.

UC202218298 EE-spyral-tech-sheet-en-we-7049684 © 2022 Medtronic. All rights reserved. Medtronic, Medtronic logo, and Engineering the extraordinary are trademarks of Medtronic. All other brands are trademarks of a Medtronic company.

medtronic.eu/RDN