Medtronic

We're here for you at every turn

By partnering together, you can leverage our breadth of experience, extensive clinical evidence, and unwavering dedication to delivering hypertension solutions – like the Symplicity™ blood pressure procedure.

We're here for you at every turn so you can:

Activate

a hypertension care pathway or a Symplicity™ renal denervation program

- Care pathway and care team development
- Patient identification and screening tools
- Reimbursement resources for physicians and patients

Advance

clinical expertise with education and training

- Hypertension disease state and treatment awareness
- Procedural training and technical skill development
- Guidance for incorporating the Symplicity procedure into existing care pathways

Combined with exclusive one-on-one support from:

Experienced **sales representatives** providing case support and product training

Accomplished **market development specialists** helping overcome barriers and expand patient access to care

Accelerate

patient access to care

- Therapy awareness programs and education for physicians
- Targeted outreach to appropriate patients in your community
- Health equity initiatives to reach underserved populations
- Payer advocacy to support patient access

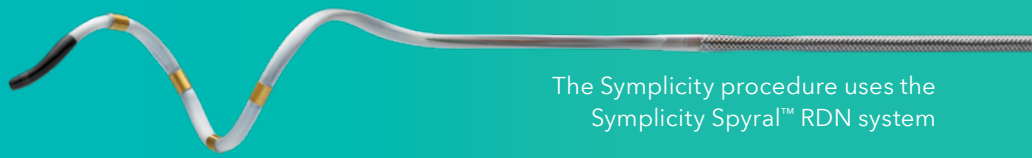
Optimize

hypertension and Symplicity programs

- Tools to spread awareness and support patients in the shared decision-making process
- Best practice sharing to improve program efficiencies
- On-demand and live education led by HTN and Symplicity program faculty experts to maximize your program

Expert **field medical education representatives** sharing deep technical knowledge

Seasoned **regional economic managers** supporting you throughout the reimbursement process



The Symplicity procedure uses the Symplicity Spyral™ RDN system

Indications
The Symplicity Spyral™ renal denervation system is indicated to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure.

Contraindications
The Symplicity Spyral system is contraindicated in patients with any of the following conditions: • Renal artery diameter < 3 mm or > 8 mm • Renal artery fibromuscular dysplasia (FMD) • Stented renal artery (< 3 months prior to RDN procedure) • Renal artery aneurysm • Renal artery diameter stenosis > 50% • Pregnancy • Presence of abnormal kidney (or secreting adrenal) tumor • Iliac/femoral artery stenosis precluding insertion of the catheter.

Warnings and Precautions
A thorough understanding of the technical principles, clinical applications, and risks associated with vascular access techniques and percutaneous transluminal catheterization in renal arteries is necessary before using this device.

The safety and efficacy of the Symplicity Spyral system has not been established in patients with isolated systolic hypertension or in patients with prior renal artery interventions including renal stents, renal angioplasty, or prior renal denervation. The Symplicity Spyral system has not yet been studied in patients who are breastfeeding, under the age of 18, or with secondary hypertension. • Avoid treatment with the Symplicity Spyral™ catheter within 5 mm of any diseased area or stent. • Implantable pacemakers (IPGs) and implantable cardioverter defibrillators (ICDs) or other active implants may be adversely affected by RF ablation. Refer to the implantable device's *Instructions for Use*. • The patient's heart rate may drop during the ablation procedure. • Proper pain medication should be administered at least 10 min before ablating renal nerves.

Potential Adverse Events
Potential adverse events associated with use of the renal denervation device or the interventional procedures include, but are not limited to, the following conditions: • Allergic reaction to contrast • Arterial damage, including injury from energy application, dissection, or perforation • Arterial spasm or stenosis • Arterio-enteric fistula • AV fistula • Bleeding • Blood clots or embolism • Bruising • Cardiopulmonary arrest • Complications associated with medications commonly utilized during the procedure, such as narcotics, anxiolytics, or other pain or anti-vasospasm medications • Death • Deep vein thrombosis • Edema • Electrolyte imbalance • Heart rhythm disturbances, including bradycardia • Hematoma • Hematoma – retroperitoneal • Hematuria • Hypertension • Hypotension (may cause end organ hypoperfusion) • Infection • Kidney damage including renal failure or perforation • Myocardial infarction • Nausea or vomiting • Pain or discomfort • Peripheral ischemia • Pulmonary embolism • Proteinuria • Pseudoaneurysm • Radiocontrast nephropathy • Renal artery aneurysm • Skin burns from failure of the dispersive electrode pad • Stroke • Other potential adverse events that are unforeseen at this time.

Please reference appropriate product *Instructions for Use* and *User Manual* for more information regarding indications, contraindications, warnings, precautions, and potential adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

For further information, please call and/or consult Medtronic at 707-525-0111 or Medtronic's website at medtronic.com.

Medtronic

Medtronic
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LifeLine Customer Support
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Product Services
Tel: 888.283.7868

medtronic.com/SymplicityProcedure

Learn more about the Symplicity procedure at **medtronic.com/SymplicityProcedure.**