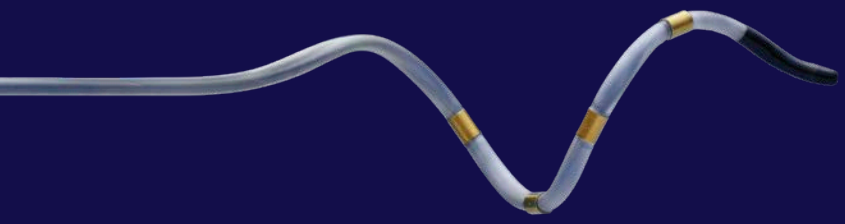
Medtronic

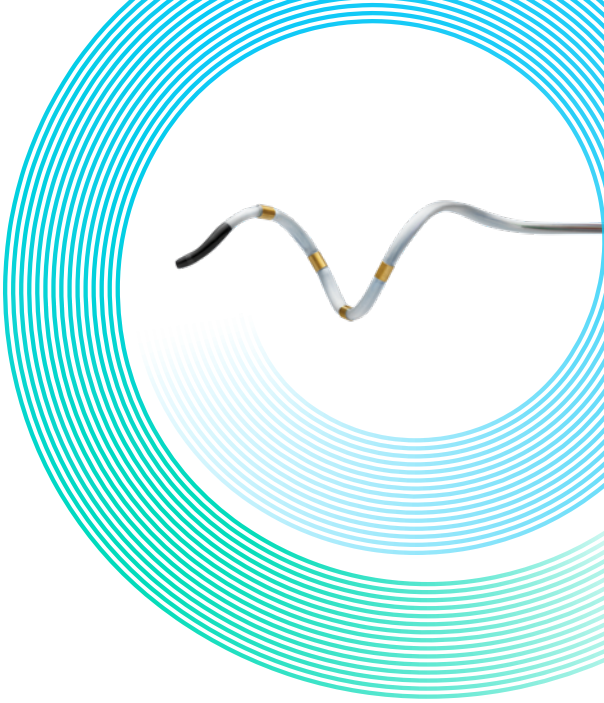


Patient examples

for the Symplicity™ blood pressure procedure

As you consider the Symplicity procedure for your patients, understanding who may be the right fit is important. Download this brochure to see some examples.

What is the Symplicity blood pressure procedure?



The Symplicity procedure is the latest treatment option available to help patients with hypertension achieve blood pressure control, complementing medications and lifestyle changes.[1]

The procedure uses the Symplicity Spyral™ renal denervation system, which is proven to deliver significant, safe, and sustained blood pressure reductions.[2-5]

See additional product information

View detailed clinical evidence

Your patients may benefit from this procedure if they:

Have uncontrolled hypertension

Consider patients where lifestyle modifications and antihypertensive medications haven't adequately controlled blood pressure.

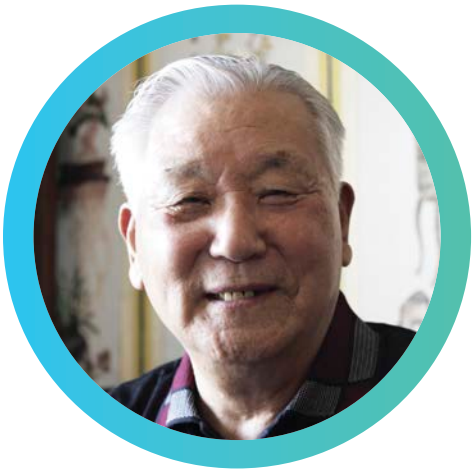
Are willing to undergo an interventional procedure

Consider patients who opt for the Simplicity procedure following shared decision-making and an attempt at lifestyle modifications and medical therapy.

1 in 3 patients

would be willing to consider an interventional approach to manage hypertension versus an additional medication. (N = 400)[6,7]

Types of patients to consider for the Symplicity procedure



Cardiovascular comorbidities

Mark
74-year-old male
BP 178/96

On three medications

Mark is diligent about taking his medication, but his history of MI has made controlling his blood pressure more urgent. Mark has an eGFR of 50, and he is prediabetic.

Treated, not controlled

Estelle
68-year-old female
BP 170/92

On five medications, including a diuretic

Estelle is on five medications, including one diuretic, and is using breakthrough hydralazine during the day. She's had two hospitalizations due to hypertension-related crises. The swelling in her legs from ACE inhibitors also makes getting around challenging.

Nonadherent due to side effects

Henry
48-year-old male
BP 154/105 with BP variability during nonadherent periods

Tried five medications; currently on one

Henry was diagnosed with hypertension at 38 when he started experiencing severe headaches. He's tried several medications and is currently on clonidine. Fatigue and other side effects of the medication, however, have taken a toll on the busy life as a father of three, and in turn have made him less adherent to his medication.

Results may vary.

Case descriptions for educational purposes; not real patient cases.

Types of patients to consider for the Symplicity procedure

Patient preference

Gabriela
59-year-old female
BP 160/91

On three medications

Both of Gabriela's parents had hypertension, and one of them passed away from a stroke. Since then, she's been careful to remain active and maintain a good diet, but she's been frustrated to see her blood pressure remain high.

Anxiety around her blood pressure is starting to make Gabriela fearful of doing things she likes to do, like travel. She is open to any options, including procedural, to help supplement all she's done to improve her condition.

Medication allergies

Jake
36-year-old male
BP 160/95

Tolerates two medications after trying several others

Jake was diagnosed with high blood pressure one year ago. Despite trying diet and lifestyle modifications, he has struggled to get it under control. Jake is allergic to many of the medications available.

Results may vary.
Case descriptions for educational purposes; not real patient cases.

Other patient factors to keep in mind

Patients who continue to struggle with uncontrolled hypertension, despite making lifestyle changes and taking antihypertensive medications, could include those who are:

- On medications that are not adequately lowering blood pressure
- Unable to adhere to medication
- Unable to tolerate medication side effects
- Are already on medication for comorbidities that may not be compatible with antihypertension medication

This is the turning point in hypertension care

Lifestyle changes and medications have defined hypertension care – until now. Visit our website to explore this proven therapy[2–5] or connect with a Medtronic representative to learn more.

Explore the Symplicity procedure

Connect with a representative

Not every person will experience the same results. The Medtronic Symplicity blood pressure procedure does have known risks. These risks should be considered in relation to the potential benefits of the procedure.

1. Medtronic Symplicity Spyral multi-electrode renal denervation catheter Instructions for Use.

2. 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.

3. Mahfoud F, et al. Outcomes following radiofrequency renal denervation according to antihypertensive medications: subgroup analysis of the Global SYMPLICITY Registry DEFINE. EuroPCR 2023.

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. *Lancet*. May 2, 2020;395(10234):1444–1451.

5. Kandzari D, Townsend RR, Kario K, et al. Safety and Efficacy of Renal Denervation in Patients Taking Antihypertensive Medications. *J Am Coll Cardiol*. November 7, 2023;82(19):1809–1823.

6. Kandzari DE, Weber MA, Poulos C, et al. Patient Preferences for Pharmaceutical and Device-Based Treatments for Uncontrolled Hypertension: Discrete Choice Experiment. *Circ Cardiovasc Qual Outcomes*. January 2023;16(1):e008997.

7. Symplicity Spyral™ Renal Denervation System. Sponsor Presentation. Presented at: US FDA Circulatory Systems Devices Panel. August 23, 2023. Available at: https://www.fda.gov/media/171691/download. Accessed July 8, 2024.

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 800-633-8766 or the Medtronic website at medtronic.com.

Medtronic

Medtronic
Tel: 707.525.0111

LifeLine Customer Support
Tel: 877.526.7890

Product Services
Tel: 888.283.7868

medtronic.com