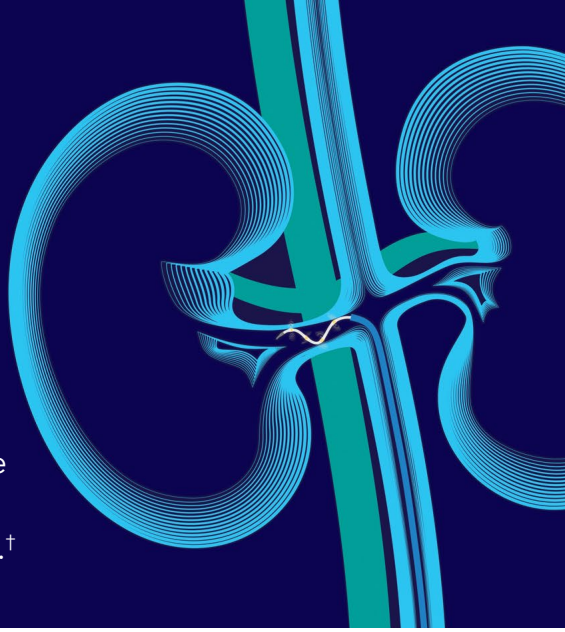
Medtronic

The Symplicity™ blood pressure procedure

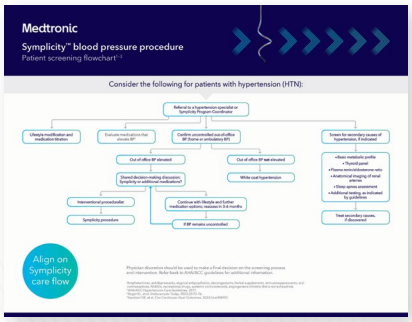
Procedure overview

Renal denervation (RDN) is another option for your patients with uncontrolled hypertension. The Symplicity blood pressure procedure is a minimally invasive procedure performed in the hospital setting. The following is an overview to help inform discussions with patients.†



Pre-procedure: Patient screening

- Patient screening for the Symplicity procedure involves:
  - Assessing lifestyle modifications
  - Evaluating medications
  - Confirming uncontrolled out-of-office blood pressure
  - Checking for secondary hypertension causes (if indicated)
- Screening can be conducted by either your team or the Symplicity care team in collaboration with a proceduralist



View the patient screening flowchart example

Symplicity blood pressure procedure

- The procedure is done in the hospital and takes about one hour, not including preparation and recovery time.
- The patient is given conscious sedation and pain medication to make them relaxed and comfortable.
- The proceduralist makes a small incision above the femoral artery on the patient's upper thigh and advances a catheter to the renal arteries. The renal anatomy is visualized to establish the treatment plan.
- Treatment is delivered with the Symplicity Spyral™ RDN system bilaterally.
- After treatment is complete, the catheter is removed. No device or implant is left behind.

Post-procedure recovery and follow-up

- Most patients can return home the same day; others may stay overnight for monitoring.
- Typically, patients resume normal activities a week after the procedure.
- After procedure follow-up, the patient is returned to the managing clinician for ongoing care.
- Documentation of OSBP/ABPM is recommended at one month, three months, and six months post-procedure.

Your patients may benefit from the Symplicity procedure if they:

Have uncontrolled hypertension[1]

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

Are willing to undergo an interventional procedure[1]

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

1 in 3

patients would consider the Symplicity procedure vs. taking one additional antihypertensive medication.[2]

Physician discretion should be used to make a final decision on the screening process and intervention. Refer back to AHA/ACC guidelines for additional information.

† For a complete overview of the Symplicity blood pressure procedure, including indications, contraindications, warnings, and instructions for use, please consult the Instructions for Use at www.Medtronic.com/manuals.

1. Kandzari DE, 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.
2. 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.

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