Medtronic

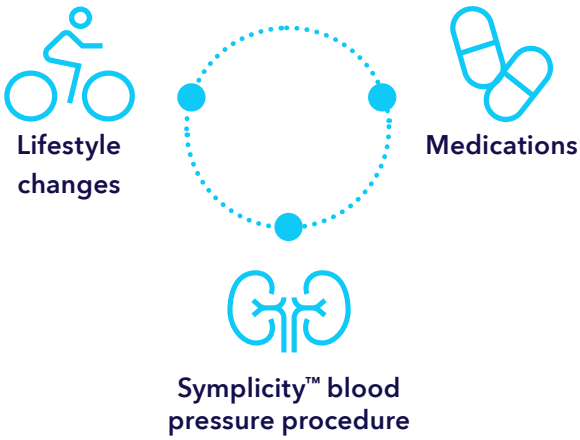
Symplicity™ Spyral
renal denervation system

Patient selection guide

for the Symplicity™ blood pressure procedure

Are you considering the Symplicity procedure for your patients? Review patient selection criteria and patient examples to easily understand who may be the right fit.

What is the Symplicity blood pressure procedure?



The Symplicity procedure is an innovative treatment option available to help patients with hypertension achieve blood pressure control, in addition to medications and lifestyle changes.[1]

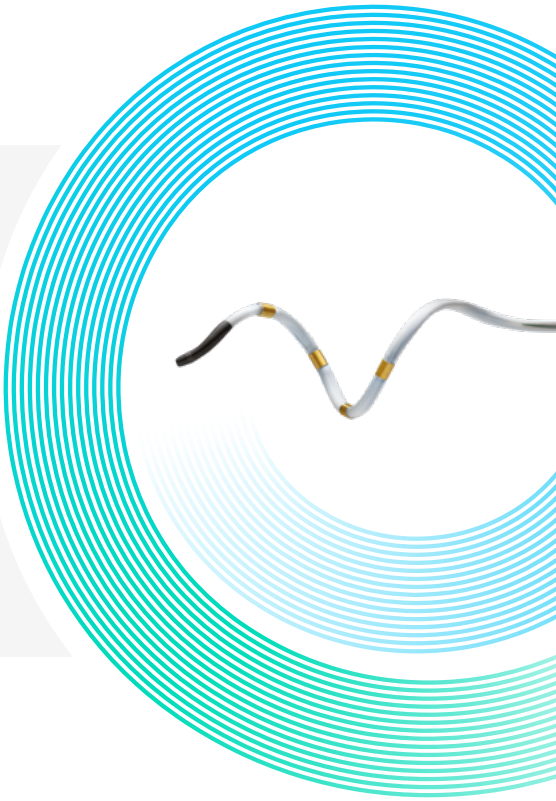
The procedure uses the Symplicity Spyral™ renal denervation system, which is proven to deliver significant, safe, and sustained blood pressure reductions.[2-5]

See additional product information

View detailed clinical evidence

Recommended by societies

2024 European Society of Cardiology **(ESC)** Guidelines[6] and 2023 European Society of Hypertension **(ESH)** Guidelines[7] **recommend renal denervation** as a safe and effective complementary treatment option for patients with uncontrolled or resistant hypertension.



Patient selection criteria

Based on the recent guidelines[6,7], patients should be considered for renal denervation if they have office blood pressure **>140/90 mmHg** and meet **one of the following criteria:**

Uncontrolled hypertension with:

- eGFR >40 ml/min/1.73m^2
- can be on fewer than 3 antihypertensive drugs
- increased CV Risk

Resistant hypertension with:

- eGFR >40 ml/min/1.73m^2
- ≥3-drug combination (incl. a diuretic)*

Intolerant to medications:

- Regardless of medication burden

Prior to the procedure, the following steps must occur[6,7]

1. **Confirm** uncontrolled out-of-office blood pressure (Home or Ambulatory BP)
2. Rule out **secondary causes** of hypertension
3. **Shared decison-making** process after assessment by a multidisciplinary team. **Patient preference** is an important consideration in the shared decision-making process as highlighted in guidelines[6,7]

1 in 3 patients would be willing to consider an interventional approach to manage hypertension versus an additional medication. (N = 400)[8,9]

* Including a thiazide or thiazide-like diuretic

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.

Multiple drugs, 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 amlodipine 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 he couldn't tolerate, 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.

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. She is frustrated about her blood pressure and anxiety is making her fearful of doing things she likes to do. She is open to any options to help 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.

Refer your patient

Once you have identified your patient, you should refer them to an **experienced RDN center.**

To find a clinic near you, visit the Medtronic website or reach out to a Medtronic representative.

Find a clinic near you

Access more resources

Explore additional tools to support patient selection for renal denervation, including educational videos, a handy pocket guide, and more.

Access referral resources

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 inthe 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. JACC Adv. 2025 Mar;4(3):101606.
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. McEvoy et al. European Heart Journal ehae178. ttps://doi.org/10.1093/eurheartj/ehae178
7. Mancia G. et al. Journal of Hypertension 2023, 41(12):1874-2071 DOI:10.1097/HJH.0000000000003480
8. 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.
9. 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.

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