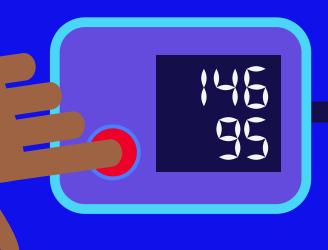
Medtronic

The Symplicity[™] blood pressure procedure

A proven way to help reduce high blood pressure¹⁻³

Beyond lifestyle changes.
Beyond medications.
Beyond expectations.



Patient guide

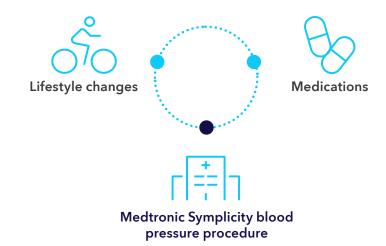
Hypertension and available treatments

High blood pressure often has no symptoms but raises serious health risks4.

- Affects men and women of all ages and health backgrounds
- Raises the risk of heart attacks, strokes, heart failure, and kidney failure^{5,6}
- These risks can be serious–especially if high blood pressure is untreated

For a long time, the only way to treat high blood pressure was through lifestyle changes, like diet and exercise, and medications.

Today, there is another approach called the Medtronic Symplicity blood pressure procedure, also known as renal denervation.



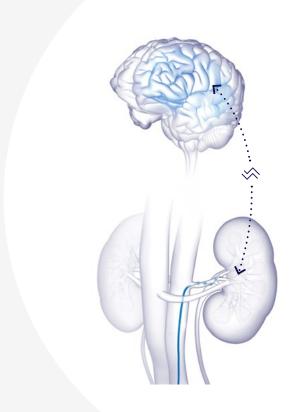
What is the Medtronic Symplicity blood pressure procedure?

- Single, minimally invasive procedure that is proven to be safe and effective^{1,2}
- Keeps working 24 hours a day–like a pill you never have to remember to take^{1,2}
- Excellent safety record with zero device or procedural safety events up to three years¹⁻³

How does it work?

Your body controls blood pressure many ways. Your heart and blood vessels are involved, as well as your kidneys⁷. In some people, the nerves connected to the kidneys experience excessive activity that interrupts the natural process of control, leading to higher blood pressure⁸.

The Symplicity blood pressure procedure calms these excessively active nerves⁹ to help you get your blood pressure under control¹⁻³.



What is the data supporting the procedure?

The Medtronic Symplicity blood pressure procedure is **clinically proven** to help reduce high blood pressure safely and effectively^{1,2}.

-16.7 mmHg

blood pressure reduction in a three-year study of people who received the procedure and also took prescribed medications¹⁰ >25,000

people treated with the Symplicity blood pressure procedure¹¹

What are the benefits for you?

The Symplicity blood pressure procedure helps reducing high blood pressure¹⁻³, which is shown to lower your risk of serious health problems¹².

Reducing your blood pressure by 10 mmHg can lower your risk of:

£B ****27%

፝ \$\ \ 17%

₹ \$ 20%

Stroke¹²

Coronary artery disease¹²

Cardiovascular events¹²

Who can the Symplicity blood pressure procedure help?

The Symplicity blood pressure procedure provides another treatment option for people with **uncontrolled high blood pressure**, no matter how many medications you have tried or when you were diagnosed. It is proven to safely help lower blood pressure in people who are taking blood pressure medication and those who are not^{1,2}.



- Taking blood pressure meds
- Not taking blood pressure meds



- Diagnosed recently
- Diagnosed years ago



- Moderately high blood pressure
- Severely high blood pressure





Is this procedure right for you?

The Medtronic Symplicity blood pressure procedure can help people who are concerned about the health risks of high blood pressure and are interested in all the available treatments.

- It's another way to get your numbers down¹⁻³ and reduce serious health risks¹¹
- It can help you achieve long-term reductions^{3,10,13} without the same side effects as medications
- While it may not affect how many medications you take, the Symplicity blood pressure procedure helps reduce high blood pressure without adding another pill to your daily regimen^{1,2}
- It may be an option for people with uncontrolled high blood pressure, no matter how many medications you have tried or when you were diagnosed



What happens now?

You will decide with your doctor if the Symplicity blood pressure procedure is right for you. What you want plays a big role in this decision, so it's important to be vocal about your preference.

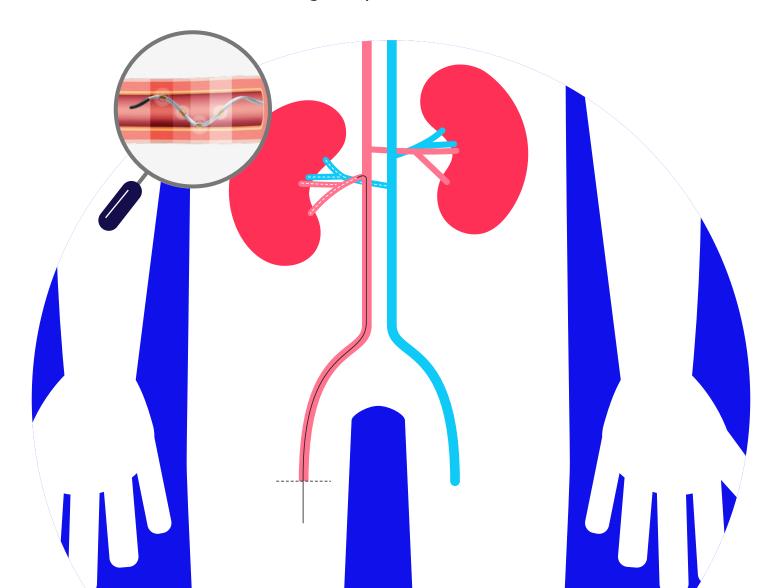
In the meantime, here are a few simple steps you can take:

- Talk to people you trust about this procedure
- Schedule time to talk with your doctor

What to expect from your procedure

1 The day of your procedure

- The procedure is done in a hospital
- The procedure takes about **an hour**
- You will be given medication to make you relaxed, sleepy, and comfortable
- After you are sedated, your doctor makes a small incision and inserts a very thin tube (less than 2 mm diameter) called catheter into the artery leading to the kidney
- The doctor then uses the catheter to deliver the therapy in order to calm the excessive activity of the nerves connected to the kidney that run beside the renal arteries?
- The procedure is repeated in both sides, left and right renal arteries
- The catheter is removed, leaving no implant behind



2 After your procedure

Some people go home the same day and some stay overnight, depending on a doctor's recommendation.

Most people resume normal activities within a week after the procedure. Your doctor will decide when you can do the same.

At your doctor's discretion, you may have two follow-up appointments:

- One with the doctor who performed your procedure
- One with the doctor who treats your high blood pressure

Maintaining a healthy lifestyle after your procedure can help reduce your blood pressure:

- Getting your blood pressure checked
- Following your doctor's advice
- Taking blood pressure (and other) medication as prescribed
- Making healthy choices about diet, exercise, and smoking



References

- 1. 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, randomized, sham-controlled trial. The Lancet 2020; Published online March 29, 2020. DOI: 10.1016/S0140-6736(20)30554-7.
- 2. Kandzari DE, Townsend RR, Kario K, at al. Safety and Efficacy of Renal Denervation in Patients Taking Antihypertensive Medications. J Am Coll Cardiol. 2023;82(19):1809-1823.
- 3. 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. 2022 :399(10333):1401-1410.
- 4. World Health Organization. Hypertension fact sheet. https://www.who.int/news-room/fact-sheets/detail/hypertension. Accessed 16 March 2023
- 5. Whelton P, Carey R, Aronow W, et. al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Originally published 13 Nov 2017 https://doi.org/10.1161/HYP.0000000000000055. Hypertension 2018;71:e13-e115.
- 6. Mayo Clinic. High blood pressure dangers: Hypertension's effects on your body. https://www.mayoclinic.org/diseases-conditions/high-blood-pressure/in-depth/high-blood-pressure/art-20045868. Accessed on 22 Jan 2024
- 7. American Heart Association. How High Blood Pressure Can Lead to Kidney Damage or Failure. https://www.heart.org/en/health-topics/high-blood-pressure/health-threats-from-high-blood-pressure/how-high-blood-pressure-can-lead-to-kidney-damage-or-failure. Accesses 22 Jan 2024
- 8. Sata Y, Head G, Denton K, et al. Role of the Sympathetic Nervous System and Its Modulation in Renal Hypertension. Frontiers in Medicine, 2018.
- 9. Coates P, Tunev S, Trudel J, Hettrick DA. Time, Temperature, Power, and Impedance Considerations for Radiofrequency Catheter Renal Denervation. Cardiovasc Revasc Med. September 2022;42:171-177
- 10. Mahfoud F. Presented at EuroPCR 2023. Includes Symplicity Spyral™ ad Flex™ catheters.
- 11. Medtronic Data on File, RDN Catheter Historic Data, June 2023. Includes Symplicity Spyral™ and Flex™ catheters
- 12. Ettehad D, Emdin CA, Kiran A, et al. Blood pressure lowering for prevention of cardiovascular disease and death: a systematic review and meta-analysis. The Lancet. 2016;387:957-67.
- 13. Mahfoud F, Mancia G, Schmieder RE, et al. Outcomes Following Radiofrequency Renal Denervation According to Antihypertensive Medications: Subgroup Analysis of the Global SYMPLICITY Registry DEFINE. Hypertension. 2023;80(8):1759-1770.

Information contained herein is not medical advice and should not be used as an alternative to speaking with your doctor. Discuss indications, contraindications, warnings, precautions, adverse events and any further information with your health care professional.

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

UC201802888b-symplicity-spyral-patient-brochure-en-emea-11460993 © Medtronic 2023. Not for distribution in the USA, Japan, or France.