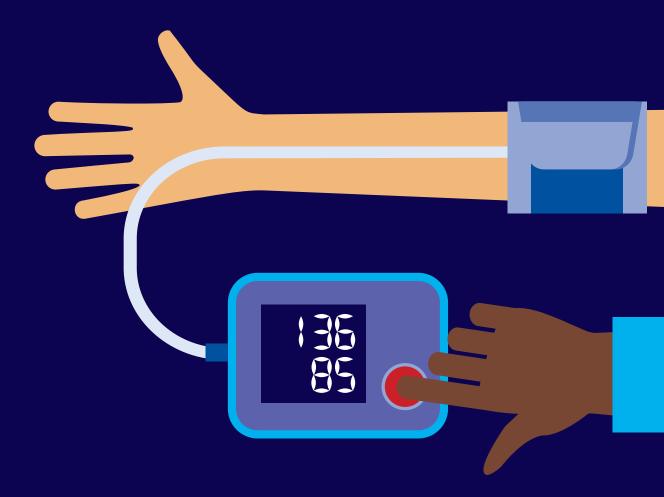
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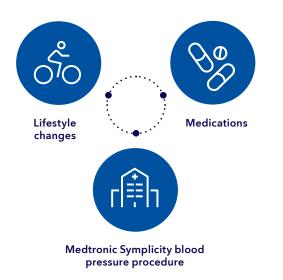
Beyond lifestyle changes. Beyond medications.

The Symplicity[™] blood pressure procedure

A new complementary treatment for high blood pressure.



Think beyond the typical treatments



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

Today, there is another approach called the Medtronic Symplicity blood pressure procedure.

The health risks of high blood pressure

High blood pressure often has no warning signs – so you could have it and not know it.¹

- Symptoms of high blood pressure (if they occur) can be mild or severe, including headaches, nosebleeds, and shortness of breath.¹ Symptoms of severe high blood pressure include severe chest pain, severe headache with confusion and blurred vision, nausea and vomiting, severe anxiety, and seizures.¹
- If you have high blood pressure, your heart works harder, which can raise your risk of heart attacks, strokes, heart failure, and kidney failure.^{2,3} These risks can be very serious especially if your high blood pressure is left untreated.
- U.S. guidelines from the American Heart Association define high blood pressure as any value greater than 130/80 mmHg.²

// I'm seeing a reduction in my blood pressure."

 Paul, patient with high blood pressure who received the Symplicity blood pressure procedure



Treat your high blood pressure safely and effectively

The Medtronic Symplicity blood pressure procedure is proven to be safe and effective in reducing high blood pressure.^{4,5}

What is it?

- A minimally invasive procedure that goes beyond the typical high blood pressure treatments and is proven to get results.^{4,5}
- Keeps working 24 hours a day like a pill you never have to remember to take.^{4,5}

How does it work?

Your body controls blood pressure many ways. Your heart and blood vessels are involved, as well as your kidneys.⁶ In some people, the nerves connected to the kidneys experience excessive activity that interrupts the natural process of control, leading to higher blood pressure.⁷

The Symplicity blood pressure procedure calms excessively active nerves connected to the kidneys that may be contributing to your high blood pressure.⁸

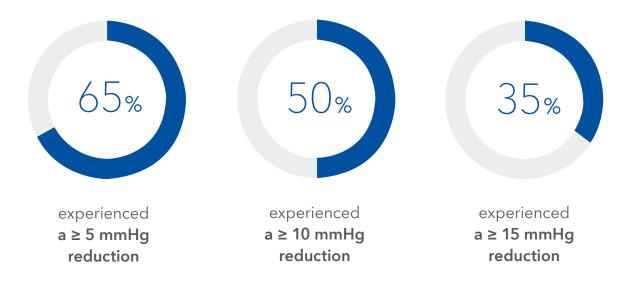


See how the Symplicity blood pressure procedure works.

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.

Proven to help reduce blood pressure beyond medications^{4,5}

In two clinical studies of people who were off and on medications after receiving the procedure^{†4,5,9}:



This means the Symplicity blood pressure procedure can work whether you are already taking medication or not.



Reducing serious health risks

The Symplicity blood pressure procedure may reduce high blood pressure,^{4,5} which is shown to lower your risk of serious health problems.¹¹ This means less worry about your future.¹⁰

Reducing your blood pressure by 10 mmHg can lower your risk of¹¹:







↓28% heart failure

€B ↓27% stroke

> 25,000 people treated with the Symplicity blood pressure procedure.¹²

What to expect from your procedure

The Medtronic Symplicity blood pressure procedure may help get your numbers moving in the right direction.^{4,5}



The day of your procedure

- The procedure is done in a hospital
- Some people go home the same day. Others stay overnight. Your doctor will decide what is right for you.
- Every hospital has its own approach, but generally speaking, the procedure takes about an hour. This does not include the time it takes to prepare for or recover from the procedure.
- 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 (catheter) into the artery leading to the kidney. The doctor then uses this device to calm the excessive activity of the nerves near the kidney. The tube is removed, leaving no device behind. You may experience some pain during the procedure.

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.

I'm feeling more vibrant and energetic."

 Paul, patient with high blood pressure who received the Symplicity blood pressure procedure



After your procedure

You may experience some bruising following the procedure. Your doctor will decide when you can return to your normal activities. 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

Get your blood pressure checked, follow your doctor's advice, take blood pressure (and other) medication as prescribed, and make healthy choices about diet, exercise, and smoking.

Ask your doctors about lifestyle changes that are right for you.



Who can the Symplicity blood pressure procedure help?

The Symplicity blood pressure procedure is a complementary treatment option for people with 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.^{4,5}



Taking blood pressure meds



Not taking blood pressure meds



Diagnosed recently

Find out if the Symplicity blood pressure procedure is right for you.





Diagnosed years ago



Moderately high blood pressure



Severely high blood pressure

Think beyond medication



Is this procedure right for you?

- The Medtronic Symplicity blood pressure procedure may 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 potentially get your numbers down^{4,5} and reduce serious health risks.¹¹
- It may help you achieve long-term reductions without the same side effects as medications.^{±13,14}
- While it may not affect how many medications you take, the Symplicity blood pressure procedure may help reduce high blood pressure without adding another pill to your daily regimen.^{4,5}
- It may be an option for people with 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 speak up 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.



Is the procedure covered by insurance?

Prior to the procedure, please work with your provider and insurance company to determine your specific plan coverage, as this can vary.

Important information about this procedure

The Symplicity[™] blood pressure procedure (BPP) is a minimally invasive procedure approved to help lower high blood pressure. The procedure is approved as a complement to treatments you may already be trying, such as lifestyle modifications and high blood pressure medications that might not be adequately controlling your blood pressure.

Receiving the Symplicity BPP should be based on a joint decision between you and your doctor. Consider the benefits and risks of the device and procedure. Please talk to your doctor to decide whether or not the Symplicity BPP is right for you.

If you have a pacemaker or an ICD, your doctor will follow up with steps to take ahead of the procedure if you decide it is right for you.

At the time of your procedure, your doctor may detect certain anatomical conditions (e.g., your blood vessels are too big or too small) that do not allow the blood pressure procedure to continue.

You should not receive the procedure if you cannot tolerate medications that are required for the procedure, like atropine, nitroglycerin, systemic blood thinners, or certain pain medications. These medications are to help you in case your heart rate drops too low, you experience pain, or your blood vessels tighten during the procedure. You should not receive the procedure if you are pregnant.

The Symplicity BPP has not been studied in patients: • Who are breastfeeding • Who are under 18 years old • Who have isolated systolic hypertension (only the "top number" of your blood pressure is high) • Who have secondary causes of high blood pressure • Who have had a renal stent placed less than 3 months prior to the procedure • Who had a prior minimally invasive treatment in their renal arteries (stenting, angioplasty, or prior renal denervation)

Potential risks of the Symplicity BPP (note that you may experience other problems that have not been previously observed with this procedure): • Allergic reaction to the imaging solution • Damage to your arteries • Future narrowing of your arteries • Arterio-enteric fistula (an abnormal connection between your aorta and your gastrointestinal tract) • AV fistula (an irregular connection between an artery and a vein) • Bleeding or blood clots • Bruising where the device enters your body (mild or severe) • Cardiac arrest or heart attack • Death • Deep vein thrombosis • Swelling • Slow heart rate • Infection • Low or high blood pressure • Damage to your kidneys that may cause one or both to stop working • Nausea or vomiting • Peripheral ischemia (lack of blood supply to your limbs) • Pulmonary embolism (a sudden block in your arteries that send blood to your lungs) • Pseudoaneurysm (blood collecting on the outside of a vessel wall causing a balloon-like widening) • Pain or discomfort • Skin burns from the failure of the equipment during the procedure • Exposure to radiation • Stroke

For further information, please call and/or consult Medtronic at 800-633-8766 or the Medtronic website at medtronic.com.



[†]Studies focused on 388 people on and off medications. [‡]Data available through three years.

References

- ¹ Hypertension fact sheet. World Health Organization. Available at: https://www.who.int/news-room/ fact-sheets/detail/hypertension. Accessed August 28, 2023.
- ² 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. *Hypertension*. June 2018;71(6):e13-e115.
- ³ High blood pressure dangers: Hypertension's effects on your body. Mayo Clinic. Available at: https:// www.mayoclinic.org/diseases-conditions/highblood-pressure/in-depth/high-blood-pressure/art-20045868. Accessed on August 28, 2023.
- ⁴ 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.
- ⁵ 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, shamcontrolled trial. *Lancet*. May 2, 2020;395(10234):1444-1451.
- ⁶ How High Blood Pressure Can Lead to Kidney Damage or Failure. American Heart Association. https:// www.heart.org/en/health-topics/high-blood-pressure/health-threats-from-high-blood-pressure/howhigh-blood-pressure-can-lead-to-kidney-damage-or-failure. Accessed October 11, 2023.
- ⁷ Sata Y, Head G, Denton K, May CN, Schlaich MP. Role of the Sympathetic Nervous System and Its Modulation in Renal Hypertension. *Front Med (Lausanne)*. May 29, 2018;5:82.
- ⁸ 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.
- ⁹ Symplicity Spyral[™] Renal Denervation System. FDA Presentation. US FDA Circulatory Systems Devices Panel. Meeting date August 23, 2023.
- ¹⁰ Kinderman I, Wedgegärtner SM, Mahfoud F, et al. Improvement in health-related quality of life after renal sympathetic denervation in real-world hypertensive patients: 12-month outcomes in the Global SYMPLICITY Registry. J Clin Hypertens (Greenwich). September 2017;19(9):833-839.
- ¹¹ Ettehad D, Emdin CA, Kiran A, et al. Blood pressure lowering for prevention of cardiovascular disease and death: a systematic review and meta-analysis. *Lancet*. March 5, 2016;387(10022):957-967.
- ¹² Medtronic data on file. RDN Catheter Historical Data, June 2023. Data includes both Symplicity Flex and Symplicity Spyral.
- ¹³ 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(10333):1401-1410.
- ¹⁴ Mahfoud F, Mancia G, Schmieder R, et al. Blood pressure and MACE reductions after renal denervation: 3-year Global Symplicity Registry results. Presented at PCR e-Course 2022.

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