

Medtronic

Patient Guide

Understanding your
Medtronic Symplicity™
blood pressure
procedure



Table of contents

3	Understanding high blood pressure
5	Health risks of high blood pressure
6	What is the Medtronic Symplicity™ blood pressure procedure?
7	Your Medtronic Symplicity blood pressure procedure: what to expect
7	After the procedure
8	Clinical studies
9	Benefits and risks
11	Frequently asked questions
12	References
14	Customer service
14	Glossary

This booklet is provided to doctors to help educate people living with high blood pressure about the options available for treating this condition. This information does not replace medical advice. Only a doctor can diagnose your health problem and determine which treatment is best for you. For definitions of important medical terms, please see the glossary on page 14.



Understanding high blood pressure

High blood pressure is one of the most common health issues in the U.S.¹ It can affect all genders, young and old, people who are **it** and people with health problems. Blood pressure measures the force applied to the walls of your blood vessels, arteries, as the heart pumps blood through your body. This pumping cycle has two phases:

Systolic blood pressure occurs when the heart contracts to pump blood. This is when your blood pressure is highest. Your doctor may call it the “top number.”

Diastolic blood pressure occurs when the heart relaxes after contracting. This is when your blood pressure is lowest. Your doctor may call this the “bottom number.”

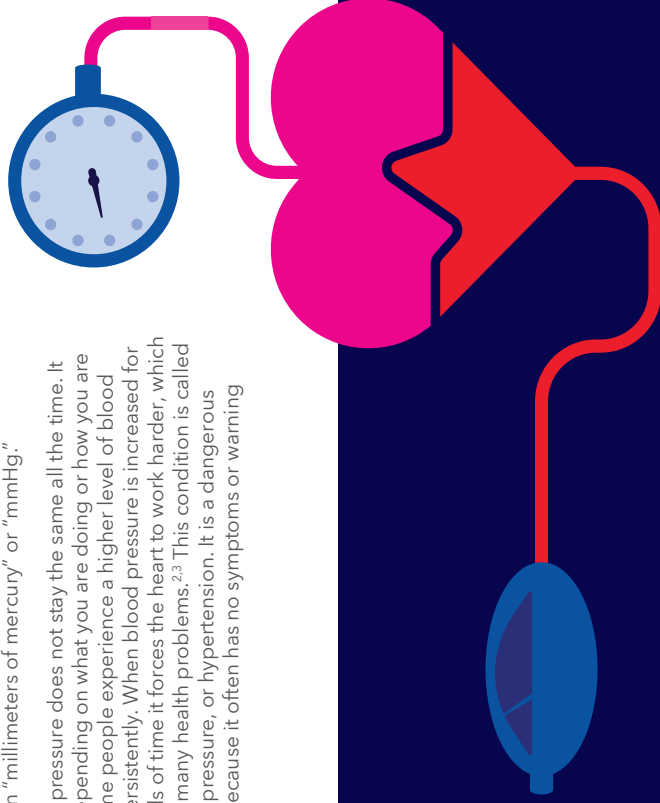
This is why your blood pressure is measured with two numbers, such as “120 over 80” or 120/80. Blood pressure is measured in “millimeters of mercury” or “mmHg.”

Your blood pressure does not stay the same all the time. It changes depending on what you are doing or how you are feeling. Some people experience a higher level of blood pressure persistently. When blood pressure is increased for long periods of time it forces the heart to work harder, which can lead to many health problems.^{2,3} This condition is called high blood pressure, or hypertension. It is a dangerous condition because it often has no symptoms or warning signs.⁴

What is considered “high blood pressure”?

It depends on the person, but there is a widely recognized definition.

U.S. guidelines from the American Heart Association **define high blood pressure as any value greater than 130/80 mmHg.**²

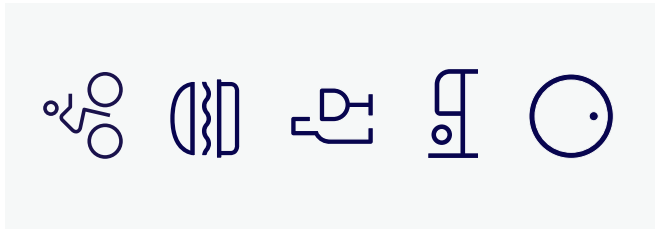


Causes

According to the American Heart Association (AHA), there are many risk factors that increase your chances of developing high blood pressure.⁵ Some you can control, and some you can't.

Risk factors that **can** be controlled include:

- Lack of physical activity
- Unhealthy diet (especially one high in salt/sodium)
- Obesity
- Drinking too much alcohol
- Sleep apnea
- High cholesterol
- Type 2 Diabetes
- Smoking and tobacco use
- Stress



Risk factors that **cannot** be changed or are difficult to control include:

- Family history of high blood pressure
- Age
- Gender
- Race
- Chronic kidney disease (CKD)

The AHA also notes that socioeconomic status and psychosocial stress are also risk factors for high blood pressure.⁵ These can affect access to basic living needs, medication, healthcare providers, and the ability to make lifestyle changes.

Prevalence

High blood pressure is extremely common. In 2020, the U.S. Surgeon General issued a “call to action” urging Americans to address it, noting that nearly half of adults have high blood pressure but only one in four have it under control.⁶

Health risks

High blood pressure often shows no symptoms which is why many people do not realize they have it.⁴ It can quietly damage your body for years. Once blood pressure remains elevated for long periods of time, it can become a serious condition. If not controlled, high blood pressure can lead to significantly increased health risks.^{2,3} Health risks associated with high blood pressure include:



Cardiovascular disease

High blood pressure can damage the cells in your arteries, as well as make the artery walls thick and stiff. Damaged or thickened arteries are known to increase your risk of cardiovascular disease.



Chest pain (angina) and heart attack

High blood pressure and other risk factors such as high cholesterol, diabetes, and smoking can cause coronary artery disease, which narrows heart blood vessels and limits blood flow to the heart muscle. When heart blood is restricted, you can experience chest pain (angina), a heart attack, or irregular heartbeat.



Stroke

High blood pressure can damage and weaken the blood vessels in your brain, causing them to narrow, rupture, or leak, leading to a stroke.



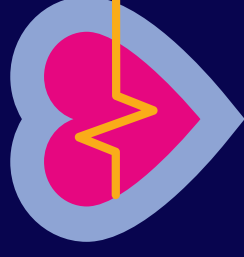
Kidney damage and failure

High blood pressure is one of the most common causes of kidney damage and failure because it can injure the large arteries leading to your kidneys and the tiny blood vessels within the kidneys.

Blood pressure treatment challenges

Healthy lifestyle habits and blood pressure medications are the first line ways to treat hypertension. However, in some people, relying on these approaches may not be enough to lower blood pressure to target levels. For example, some people with high blood pressure try to follow a healthy diet, exercise, and take medications - yet their blood pressure is still high. In others, it can be challenging to find the right medications to effectively lower blood pressure or blood pressure medications may have side effects that make them difficult or not possible to use.

The Medtronic Symplicity blood pressure procedure



What is the Medtronic Symplicity blood pressure procedure?

The Medtronic Symplicity blood pressure procedure, also known as renal denervation (RDN), is intended to help people who have not been able to get their blood pressure under control with lifestyle changes and medications. It is approved to reduce blood pressure alone or in combination with other therapies that lower blood pressure.

Your body regulates your blood pressure in different ways, using different organs, including the kidneys.⁷ Specifically, some people with high blood pressure have overactive renal nerves (called sympathetic nerves). ("Renal" is the medical word used to describe the kidneys.) When these nerves are overactive, they can interfere with how the body controls blood pressure, leading to hypertension.⁸ The Medtronic Symplicity blood pressure procedure **calms** these nerves and reduces their activity.

The RDN procedure is performed with the Medtronic Symplicity Spyral™ renal denervation system. This system, which includes the Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter used with the Symplicity G3™ Renal Denervation RF Generator delivers low-level radiofrequency (RF) energy through the wall of the renal artery to reduce the activity of nerves near the kidney.

Your doctor can help you understand if you are a good candidate for the procedure.



Your Medtronic Symplicity blood pressure procedure: what to expect

If you and your doctor decide that the Medtronic Symplicity blood pressure procedure is right for you, you should have already discussed the benefits and risks as well as what to expect. Remember, the Medtronic Symplicity blood pressure procedure may be considered if your blood pressure is not controlled despite attempts to adopt healthy habits and using blood pressure medications.

Prior to your scheduled procedure, your doctor will take your blood pressure to confirm your eligibility as well as answer any questions you may have.

The procedure usually takes about an hour for the doctor to perform, although this does not include the time to prepare you to undergo the procedure or your recovery time. Here is a step-by-step guide of what generally happens during the procedure:

- 1 The procedure is done in a hospital.
- 2 You will be given medication to make you relaxed, sleepy, and comfortable. Your doctor will administer pain medication at least ten minutes before the procedure.
- 3 After you are sedated, your doctor makes a small incision and inserts a very thin tube (catheter) into the artery leading to the kidney.
- 4 The doctor then uses the catheter to calm the nerves near the kidney.
- 5 The tube is removed, leaving no device behind.

Some people go home the same day and others stay overnight and go home the next day. Your doctor will decide what is right for you.



Figure 1:
Symplicity Spyr™
Multi-Electrode Renal
Denervation Catheter

After the procedure

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 doctors advice
- Taking blood pressure (and other) medication as prescribed
- Making healthy choices about diet, exercise, and smoking

Clinical studies

The Medtronic Symplicity blood pressure procedure is proven to reduce blood pressure.⁹

Two studies show that the procedure lowers blood pressure on people whether or not they are taking blood pressure medications.¹²⁻¹⁴

In these two studies, patients who underwent the procedure (the RDN group) had greater blood pressure reduction compared to patients who did not receive the procedure (the Control group). In study of people taking blood pressure medication (Figure 1), at 6 months blood pressure measured at the Doctor's office in patients in the RDN group dropped 9.9 mmHg, while those in the Control group had only a 5.1 mmHg blood pressure drop.¹⁰ These results are an average for the entire study. For context, 51% of the patients treated with RDN in this study saw their blood pressure drop by more than 10 mmHg compared to 39% of the Control group.

In study of people not taking blood pressure medication for three months, (Figure 2), the blood pressure measured at the Doctor's office in the RDN group at 3 months, dropped 9.4 mmHg, while those in the Control group had only a 2.3 mmHg drop. For context, approximately 50% of the patients treated with RDN in this study saw their blood pressure drop by the average measurement of about 10 mmHg. For context, 48% of the patients treated with RDN in this study saw their blood pressure drop by more than 10 mmHg compared to 25% of the Control group.

Compared to these office measurements, when blood pressure was measured with hourly readings over a 24-hour period, there was a smaller difference in the drop in blood pressure when comparing the RDN group to the Control group.

For context, studies have shown that reducing blood pressure with medications by this amount (10 mmHg) can lower your risk of:¹¹

cardiovascular events ↓ 20%
heart failure ↓ 28%
stroke ↓ 27%

Figure 1

Blood pressure reduction (mmHg) measured at the Doctor's office 3 months after the procedure in patients not taking blood pressure medications²⁰



Figure 2

Blood pressure reduction (mmHg) measured at the Doctor's office 3 months after the procedure in patients taking blood pressure medications²⁰



⁹ Baseline systolic blood pressure (Figures 1-4): 163 mmHg

Benefits and risks



Benefits

Talk with your doctor about potential benefits associated with the procedure.

Two clinical studies (see Clinical Studies section for more detail) show that the Medtronic Symplivity blood pressure procedure reduces blood pressure. In addition to taking blood pressure medication, eating healthier and exercising, the Medtronic Symplivity blood pressure procedure may help reduce your blood pressure. This is important because even small reductions in blood pressure can reduce the risk of cardiovascular events.^{1,6}

Important Safety Information

The Symplivity™ 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 Symplivity 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 Symplivity 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.

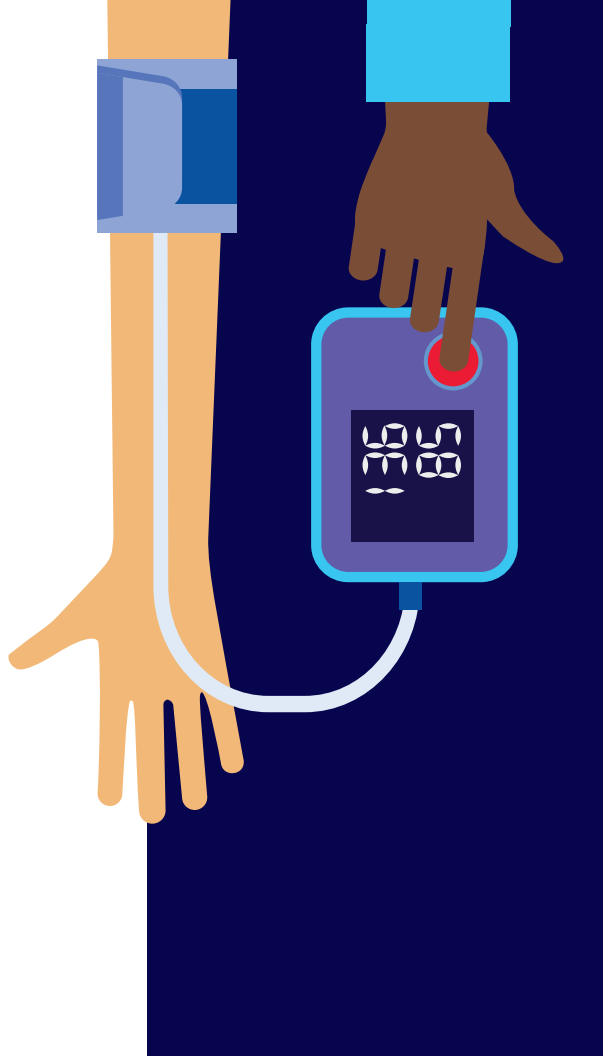
The Symplivity BPP has not been studied in patients:

- 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 Symplivity 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
- Stroke

For further information, please call and/or consult Medtronic at the toll-free numbers or websites listed.



Frequently asked questions

If you are interested in the Medtronic Symplicity blood pressure procedure, talk with your doctor about its potential benefits and risks. In the meantime, here are answers to some of the most common questions about it.

Who could potentially benefit from the Medtronic Symplicity blood pressure procedure?

Generally, the Medtronic Symplicity blood pressure procedure is for people who have been unable to control their blood pressure with medication or lifestyle changes. Together with your doctor, you can decide whether this procedure is right for you.

How long does the procedure last?

The procedure typically takes about an hour to perform. Some people go home the same day and others stay overnight and go home the next day. Your doctor will decide what is right for you.

Will anything be implanted in my body?

No. The Medtronic Symplicity blood pressure procedure does not require a permanent implant of any kind.

When can I return to normal activities after the Medtronic Symplicity blood pressure procedure?

Most people resume normal activities within a week. Your doctor will decide when the time is right for you.

Will my kidneys work the same as they did before the procedure?

Every patient is different. However, clinical trial information through 2 years following this procedure has shown no negative effect on kidney function.^{3,14-16}

Should I keep taking my medication after the Medtronic Symplicity blood pressure procedure?

Yes. Continue taking all blood pressure (and other) medication as prescribed unless your doctor recommends a change.

Customer service

Medtronic is committed to providing quality customer service. Feel free to contact us at 1-800-633-8766.

Glossary

Medtronic Symplicity Blood Pressure Procedure

Another name for renal denervation, a procedure designed to lower blood pressure by calming the activity of nerves near the renal arteries.

Contraindications

Symptoms, conditions, or other factors that may mean you should not receive a specific medical procedure.

Diastolic blood pressure

Your blood pressure when the heart relaxes after contracting. This is when your blood pressure is lowest. Also known as the “bottom number” in a blood pressure reading.

Hypertension

The medical term for high blood pressure.

mmHg

Millimeters of mercury, the unit of measurement for blood pressure, where “mm” stands for millimeters and “Hg” stands for mercury. This unit is equal to the pressure that can support a column of mercury one millimeter high.

OSBP

Office systolic blood pressure. A measure of blood pressure taken in a doctor’s office.

Renal

Relating to, involving, or located in the region of the kidneys.

Renal denervation

A minimally invasive procedure designed to lower blood pressure by calming the activity of the nerves near the renal arteries.

Radiofrequency energy

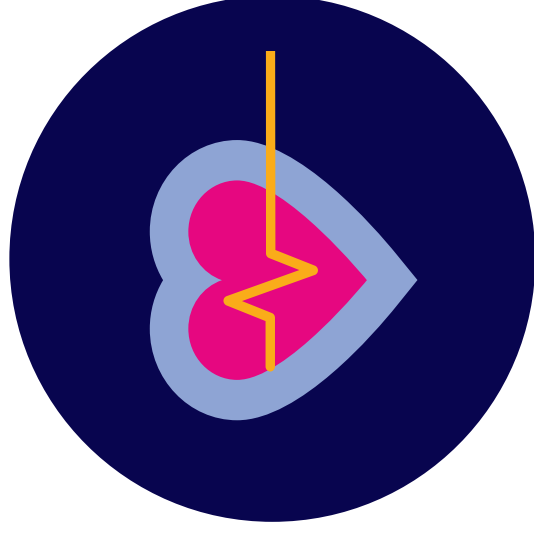
A type of energy used to heat up the tissues inside the nerve vessel and calm nerve activity.

Systolic blood pressure

Your blood pressure when the heart contracts to pump blood. This is when your blood pressure is highest. Also known as the “top number” in a blood pressure reading.

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- ²⁰ Symplicity Spyral™ Renal Denervation System. FDA Presentation. US FDA Circulatory Systems Devices Panel. Meeting date August 23, 2023. Pg 33, 48, 182. patients off medications, 206 patients on medications.



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