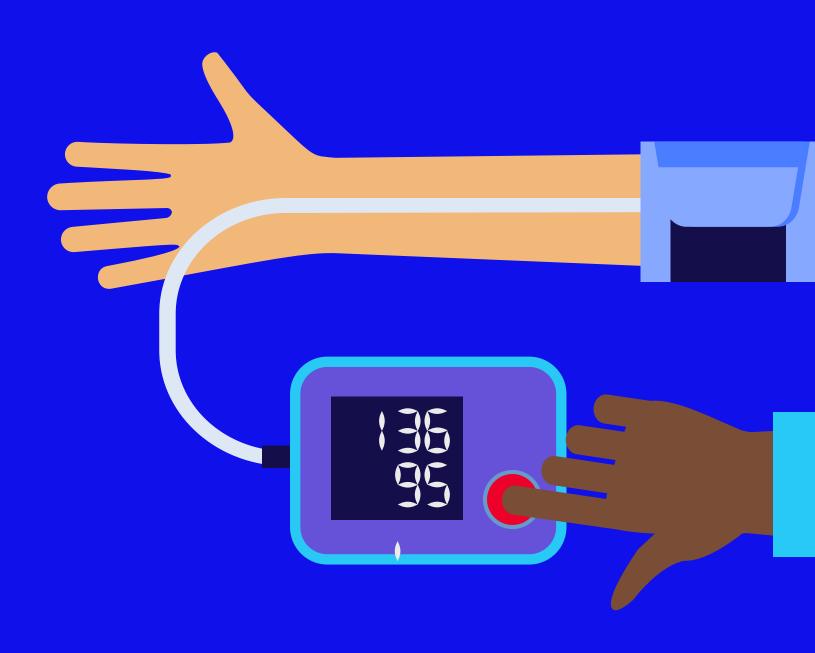
#### Medtronic

### Complements lifestyle changes. Complements medications.

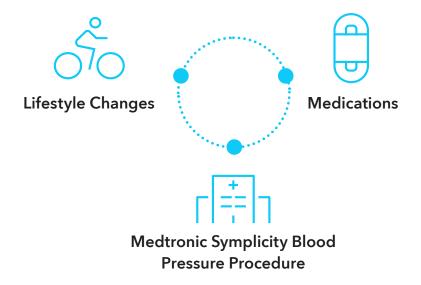
#### The Symplicity™ Blood Pressure Procedure

A proven way to help reduce high blood pressure<sup>1-3</sup>



### Adjunctive to the typical management options

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



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

The Symplicity blood pressure procedure expands the typical hypertension management options, offering a single, minimally invasive approach that is proven to get results.<sup>1-3</sup>

Adverse events include, but are not limited to, bruising and pain. Results may vary.



#### The health risks of high blood pressure

High blood pressure often has no symptoms but raises serious health risks.<sup>4</sup>

- Affects men and women of all ages and health backgrounds
- Raises the risk of heart attacks, strokes, heart failure, and kidney failure<sup>5,6</sup>
- These risks can be serious-especially if high blood pressure is unmanaged

# I took back my day-to-day activities.

-Mary, patient with high blood pressure who received the Symplicity blood pressure procedure



### Manage your high blood pressure safely and effectively<sup>1,2</sup>

The Medtronic Symplicity blood pressure procedure is a safe and effective way to help reduce high blood pressure.

#### What is it?

- Single, minimally invasive procedure that is proven to be safe and effective<sup>1-3</sup>
- Keeps working 24 hours a day-like a pill you never have to remember to take<sup>1,2</sup>
- Excellent safety record with zero device or procedural safety events through three years<sup>1-3</sup>



#### How does it work?

Your body controls blood pressure many ways. Your heart and blood vessels are involved, as well as your kidneys.<sup>7</sup> In some people, the nerves connected to the kidneys experience excessive activity that interrupts the natural process of control, leading to higher blood pressure.<sup>8</sup>

The Symplicity blood pressure procedure calms these excessively active nerves to help you get your blood pressure under control.<sup>1-3</sup>

#### Who can the Symplicity blood pressure procedure help?

The Symplicity blood pressure procedure provides an adjunctive management 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.<sup>1,2</sup>



- Taking blood pressure meds
- Not taking blood pressure meds



- Diagnosed recently
- Diagnosed years ago



- Moderately high blood pressure
- Severely high blood pressure



### Proven to help reduce blood pressure<sup>1-3</sup>

The Medtronic Symplicity blood pressure procedure is clinically proven to help reduce high blood pressure safely and effectively.<sup>1-3</sup>

### -16.7 mmHg

blood pressure reduction in a three-year study of people who received the procedure and also took prescribed medications<sup>9</sup>

>20,000

people managed with the Symplicity blood pressure procedure<sup>†10</sup>

#### Reducing serious health risks

The Symplicity blood pressure procedure reduces high blood pressure,1-3 which is shown to lower your risk of serious health problems.<sup>11</sup> This means less worry about your future.<sup>12</sup>

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

₹20%

cardiovascular events<sup>11</sup>



**↓**28%

heart failure<sup>11</sup>



**↓**27%



### What to expect from your procedure

The Medtronic Symplicity blood pressure procedure can help get your numbers moving in the right direction.<sup>1-3</sup>

- 1 The day of your procedure
  - The procedure is done in a hospital
  - Some people go home the same day and some stay overnight, depending on a doctor's recommendation
  - 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 (catheter) into the artery leading to the kidney. The doctor then uses the catheter to calm the excessive activity of the nerves connected to the kidney. The tube is removed, leaving no implant behind.

# Grab this therapy with both hands.

#### After your 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 manages 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



## Complements medications and lifestyle change



#### 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 management options.

- It's another way to get your numbers down<sup>1-3</sup> and reduce serious health risks<sup>11</sup>
- It can help you achieve long-term reductions without the same side effects as medications<sup>1,2</sup>
- 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<sup>1,2</sup>
- It may be an adjunctive therapy 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



#### Scan to learn more



#### Important information about this procedure

The Medtronic Symplicity™ blood pressure procedure, just like any medical procedure, has risks. However, clinical studies show that these risks and side effects are rare.¹,²

The safety and effectiveness of the Blood Pressure Procedure have not been evaluated in patients who are pregnant, nursing, or who are younger than 18 years old.

Careful consideration should be given to use of the Blood Pressure Procedure in patients with aortic grafts or who have received a renal stent in the last three months.

Implantable pacemakers and implantable cardioverter/defibrillators (ICDs) may be adversely affected by RF ablation. If you have a pacemaker or ICD, your doctor will follow up with steps to take before receiving the Blood Pressure Procedure.

You should not receive the Blood Pressure Procedure if:

- You have an allergy or suspected allergy to nitinol
- You cannot tolerate atropine, nitroglycerine, or systemic anticoagulation medication
- A reduction in your blood pressure would be considered hazardous to your health
- Your doctor determines that your arteries are too narrow or too wide for the catheter

Since you may experience pain when radiofrequency energy is delivered, your doctor will deliver pain medication at least five minutes prior to the procedure.

Your heart rate may drop during the ablation procedure. If this happens, your doctor will administer medication to bring your heart rate back up.

Intervention risks: death, cardiopulmonary arrest, heart rhythm, disturbances, including bradycardia, formation of blood clots and/or embolism (which may result in ischemic events such as myocardial infarction, pulmonary embolism, stroke, kidney damage, or peripheral ischemia), retroperitoneal hematoma, hematoma, bruising, bleeding, arterial damage, arterial spasm, arterial stenosis, arterial dissection or perforation, renal artery aneurysm, kidney perforation, pseudoaneurysm, AV fistula, pain, skin burns, and thermal injury to the vasculature or other structures from energy application.

Contrast agents, narcotics, anxiolytics, other pain medications and anti-vasospasm agents are also commonly used during the procedure or after the procedure; use of these agents is associated with known risks.

Other risks include: proteinuria, hematuria, electrolyte disturbances, worsening renal function, hypotension, hypotension causing end organ hypoperfusion, nausea, and vomiting.

Biological hazards: risks of infection, toxicity, abnormal hematology profile, allergy, hemorrhage, and pyrogenicity.

Environmental hazards: consistent with standard hospital protocols for proper use and disposal of biological wastes.

Radiation hazards: consistent with normal use of x-ray during interventional procedures.

† Includes Symplicity Spyral™ and Flex™ catheters.

#### References

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- 10. Medtronic data on file.
- 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. *The Lancet*. 2016;387:957-67.
- 12. 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. *The Journal of Clinical Hypertension*. 2017;1-7.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

