Renal Denervation (RDN) Therapy
Patient Guide

Symplicity™ Renal Denervation System
High blood pressure, also called hypertension, is a measure of the force of blood pushing against the artery walls as it flows through the body. Everyone experiences daily fluctuations in blood pressure, but typically these changes are temporary and have no lasting impact on our health. In fact, it is normal for blood pressure to vary from person to person, and to rise and fall throughout the day with changes in activity or emotional states.

Some individuals, however, experience elevated levels of blood pressure for sustained periods of time. Consistently high blood pressure forces the heart to work beyond its capacity and can be life-threatening. Just as too much air pressure can damage a tire, high blood pressure can damage arteries. High blood pressure is a serious condition that can lead to heart failure, stroke, kidney failure, coronary heart disease and other health problems.1

Causes
While hypertension can affect anyone, a poor diet, stress, hormones and lack of exercise may contribute to its onset. Certain medications may also raise your blood pressure. You may know family members with high blood pressure—hypertension is often passed down through generations.

High blood pressure can also be linked to overactive nerves in the sympathetic nervous system, which includes the major organs that are responsible for regulating blood pressure: the brain, heart, kidneys and blood vessels. Abnormally elevated nerve traffic between the kidneys, heart and brain can increase blood pressure.2

Diagnosis
Many people may not realise that they have high blood pressure. Because of its limited symptoms, hypertension is often called "the silent killer." Luckily, high blood pressure can be diagnosed with a series of blood pressure tests. Blood pressure is measured as systolic and diastolic pressures. "Systolic" refers to blood pressure when the heart beats while pumping blood. "Diastolic" refers to blood pressure when the heart is at rest between beats. Blood pressure readings are typically written with the systolic number in front of the diastolic number, such as 120/80 mmHg. The "mmHg" refers to millimeters of mercury—the units used to measure blood pressure.

People with blood pressure readings of 140/90 mmHg or higher, taken on at least two occasions, are considered to have high blood pressure. People with blood pressure readings of 200/120 mmHg or higher require immediate treatment. Individuals with diabetes are typically treated if their blood pressure rises above 130/80, since their condition already puts them at a higher risk of heart disease. If the pressure remains high, preliminary treatment is generally started.

Treatment Options for High Blood Pressure

Traditionally, patients with high blood pressure are encouraged to adopt healthy lifestyle habits and are often given antihypertensive medications. Following a disciplined treatment plan is important to reduce the problems associated with high blood pressure.

Lifestyle Changes
Controlling high blood pressure means integrating healthy habits including:

- Limiting alcohol
- Maintaining a healthy weight
- Getting plenty of exercise
- Reducing sodium intake
- Eating a diet rich in fruits and vegetables
- Reducing total fat intake
- Quitting smoking
- Managing stress

Medications
More severe cases of hypertension are treated with drug therapies. Modern antihypertensive medications are designed to work in different ways to lower blood pressure—some remove extra fluid and salt from the body, some slow down the heartbeat and others relax and widen blood vessels. For some patients, many medications work better than one to control high blood pressure.3

Unfortunately, in about half of all treated patients, lifestyle changes and medications are not enough to control high blood pressure. Some people with uncontrolled hypertension are typically called "resistant hypertensive," which means that their blood pressure is above accepted levels despite the use of three or more antihypertensive drugs one of which is a diuretic. Resistant hypertensive individuals require more aggressive treatment than lifestyle changes and medications can provide.
People with hypertension typically have overactive renal (kidney) nerves, a condition that raises blood pressure and contributes to heart, kidney and blood vessel damage. The Symplicity™ renal denervation system uses a technique called renal denervation (RDN) to selectively calm hyperactive renal nerves. This causes a reduction in the kidneys’ production of hormones that raise blood pressure and may also protect the heart, kidneys and blood vessels from further damage.

The Symplicity renal denervation system provides doctors an innovative treatment option for uncontrolled hypertension that offers several benefits including:

- Significant reduction in blood pressure
- Safe, short treatment that does not require general anesthesia
- Fast recovery time with minimal complications

Why It Works
The method of action of RDN therapy is supported by surgical hypertension treatments, called nonselective surgical sympathectomy, which were highly invasive and involved open surgery to sever the sympathetic nerves leading to the kidneys. This surgery was shown to effectively lower blood pressure yet caused significant side effects. The technique was discontinued as antihypertensive drugs became more affordable and accessible.

RDN therapy using the Symplicity renal denervation system accomplishes the same results as nonselective sympathectomy—effectively lowering blood pressure. However, it is performed with a safer, less invasive and more selective technique that carries a much lower incidence of potential complications and side effects.

How It Works
The Symplicity renal denervation system consists of a small steerable treatment catheter and an automatically-controlled treatment delivery generator. The treatment does not require open surgery. Instead, your doctor will make a tiny incision in your groin and insert a sheath, called a sheath, into your femoral (thigh) artery. A guiding catheter is then inserted through the sheath to direct the Symplicity™ catheter to the renal arteries. The Symplicity catheter delivers high-frequency radio waves, called RF waves, to 4–6 locations within each of the two renal arteries. The energy delivered is about 8 watts, similar to that used to power a flashlight. This energy delivery aims to disrupt the nerves and lower blood pressure over a period of months.

The Symplicity Renal Denervation System

The Symplicity renal denervation system is designed to quiet these nerves and reduce blood pressure.
Early Treatment Results
The Symplicity renal denervation system demonstrates promising results and has been featured at prominent medical meetings and in international medical journals. In a major study, half of the patients were treated for hypertension with lifestyle changes and medications, and the other half was treated with RDN therapy using the Symplicity renal denervation system. The patient group treated with lifestyle changes and medications saw a 1-mmHg rise in blood pressure, while the group treated with RDN therapy had an average systolic blood pressure reduction of 32 mmHg. Neither group experienced serious complications or unusual side effects.

Potential Risks
Procedures involving the insertion of a catheter into the groin to access arteries are very common in cardiovascular care; the administration of energy is new. While the complication rate for RDN therapy is very low, the potential risks associated with it are similar to those associated with all diagnostic procedures involving catheterisation of the arteries. These include but are not limited to:

- Low or high blood pressure
- Heart rhythm disturbances (for example, slow rate)
- Cardiac arrest
- Blood clot
- Mortality
- Injury to the artery that may require surgery
- Complications related to the contrast dye used
- Complications related to pain and anti-anxiety medications administered
- Additional risks that could possibly be associated with RDN therapy include but are not limited to:
  - Kidney damage
  - Injury to the artery
  - Reduction of blood pressure to low or fast, leading to complications
  - Pain
  - Infection
  - Skin burn
  - Blood or protein in urine
  - Electrolyte changes

RDN Therapy with the Symplicity Renal Denervation System
Based on your medical history, test results and symptoms, your doctor may decide that RDN therapy with the Symplicity renal denervation system is an appropriate treatment option for you.

Procedure
The procedure, which typically takes 40–60 minutes, is performed in a specialised area of the hospital called a cardiac catheterisation laboratory (‘cath lab’). For the surgery, you will receive an intravenous line (IV) to administer fluids and medications, and your blood pressure and heart rhythm will be monitored. Your upper leg will be shaved and cleaned with an antiseptic solution and sterile drapes will be placed around this area. You will receive local anaesthetic in your upper thigh to numb the area. You may feel some pressure and a burning sensation at the site, but it will only last a few seconds. During the procedure you will not need general anaesthesia, but a sedative may be given to help you relax and you may receive pain medications as needed.

Your doctor will insert a short hollow sheath into an artery in the prepped area of your thigh. Through this tube, a longer tube, called a guiding catheter, will be inserted. The catheter will be guided to the arteries that supply blood to your kidneys, and will act as a pathway for the Symplicity catheter. Special contrast dye will be injected through the guiding catheter and into your bloodstream to allow your doctor to view your arteries on an X-ray monitor, much like a television screen.

After directing the guiding catheter to the artery supplying one of your kidneys, your doctor will begin treatment by delivering RF waves to different locations within your artery. Each treatment lasts about two minutes. It is common to feel some discomfort in your abdomen during treatment, but this can usually be managed effectively with pain medication and only lasts a short time.

Once the first artery is treated, your doctor will reposition the guiding catheter to access the artery supplying your other kidney, and will begin treatment there. After all required treatments have been delivered, the treatment catheter and guiding catheter will be withdrawn from your leg.

What to Expect During Your Procedure
Follow-Up Care

After the procedure, you will be moved to an area where nurses can monitor your recovery. At this time, the sheath in your thigh may be removed and pressure may be applied (sometimes a closure device is used) to the puncture site until any bleeding has stopped. You will be instructed to lie flat for several hours and to keep your leg straight to prevent the wound from reopening. Your puncture site will be monitored closely for any signs of bleeding. Should you see any blood or feel warmth at the area of the puncture site, notify your doctor immediately. Your leg will also be monitored for any changes in color, temperature or sensation.

Once you have returned to your hospital room, you may be able to eat and drink and may receive visitors upon your doctor’s recommendation. Your doctor will also advise you when you can get out of bed and walk around.

Many patients are able to go home very soon after the procedure. The amount of time that you stay in the hospital will depend on several factors including how well your puncture wound is healing and your doctor’s guidance.

Continuing to Manage Your High Blood Pressure

After receiving RDN therapy it is important to maintain a healthy lifestyle. This involves carefully following your doctor’s advice and making good choices regarding your health:

**Stop smoking.** Smoking increases your heart rate and blood pressure, raising your risk of heart attack and stroke. If you’re ready to quit, ask your doctor for advice or to suggest smoking cessation aids to help you quit.

**Limit alcohol.** Consuming more than three alcoholic beverages in one sitting can temporarily increase blood pressure. Repeated binge drinking can lead to long-term increases of blood pressure.

**Increase your activity.** Your doctor can recommend an activity program tailored for your situation. Regular exercise can help you lower your blood pressure and blood cholesterol and help you maintain a healthy weight. It can also help you manage the daily stresses of modern life more easily.

**Choose a healthy diet.** A diet low in saturated fats, cholesterol, sodium and rich in lean protein, fresh fruits, vegetables and whole grains can help you achieve a healthy weight and control your blood pressure and cholesterol levels.

**Manage your stress.** Stress is an inescapable aspect of modern day living, but you can help lessen its negative health effects by practicing the “relaxation response.” Research has shown that relaxation techniques can improve your ability to cope with stressful events while decreasing your heart rate, blood pressure and stress hormone levels.

**Continue taking your blood pressure medication.** If you have a prescription, continue taking your medication as directed by your doctor. Blood pressure medicine only works while you are taking it. Do not stop taking the medicine or change the dosage without your doctor’s guidance. If you stop taking it, your blood pressure will go back up. If you are bothered by side effects, talk with your doctor. There are many types of blood pressure medications and you and your doctor can work together to find one that is right for you.
Will my kidneys work the same as they did before the procedure?
Clinical trials using the Symplicity renal denervation system have demonstrated normal renal function with no kidney-related complications from the procedure. Successful kidney transplants have also shown that these renal nerves are not necessary for normal kidney function. In fact, deactivating them may cause a reduction in blood pressure and protect the heart, kidneys and blood vessels from further damage caused by hypertension.

Will the procedure hurt?
Although you will be awake for the entire procedure, you will feel minimal pain. The access site will be numbed using local anesthesia, and pain medications will be administered intravenously as needed. When the catheters are inserted, most patients feel only a slight pressure or a sensation of mild tugging, but because there are no nerve endings inside the arteries, patients being catheterised cannot feel the catheters moving through them.

How does the doctor know the catheter is in the correct location?
Using a technique called fluoroscopy, a contrast dye is injected through the catheter and flows into the renal arteries. Your doctor can view the dye on the X-ray machine, which is hooked up to a monitor, and can trace the movement of the devices through your arteries.

Will anything be implanted into my body?
This procedure requires no implants.

How long does the procedure last?
The entire procedure will take about 40–60 minutes.

When can I resume my regular activities?
Your doctor will advise you. Many patients can return to work and follow their normal routines very shortly after the procedure.

Can I stop taking my antihypertensive medication following the procedure?
Your doctor will advise you about the possibility of lowering any of your medications or stopping them altogether. Be sure to discuss your medications with your doctor before stopping or changing your dosage on your own.

Artery. A vessel that carries oxygen-rich blood to the body.
Blood pressure. A measure of the force of blood pushing against artery walls as it flows through the body. During each heartbeat, blood pressure varies between a maximum (systolic) and a minimum (diastolic) pressure.
Catheter. A tube that can be inserted into a body cavity, duct or vessel, thereby allowing drainage, administration of fluids or gases, or access by surgical instruments.
Clinical studies. Regarding new medical technology, “clinical” is used to distinguish controlled studies on humans from earlier nonhuman (preclinical) studies in animal (in vivo) or laboratory (in vitro) models.
Denervation. Modifying or disabling the connection between an organ or structure and the nerves that communicate to the central nervous system.
Femoral artery. Blood vessels located in the thigh that carry blood to the groin region of each leg.
Kidney. One of two identical organs located high and deep in the abdomen that filter blood, regulate fluids, remove waste and help regulate blood pressure.
Renal. Referring to the kidneys. Renal arteries supply the kidneys with blood.
Sympathectomy. Surgical disabling of sympathetic nerves via cutting or ablation with heat or radiofrequency energy.
1. National Heart Lung and Blood Institute