Table of Contents

Treating renal artery disease .............................................................................................................2
What is renal artery disease? ...............................................................................................................3
Renal artery disease treatment options ..........................................................................................4
Risks ................................................................................................................................................5
Benefits ...........................................................................................................................................7
Summary of clinical data ...................................................................................................................8
Before your procedure .......................................................................................................................9
During a typical renal stenting procedure .......................................................................................10
After a typical renal stenting procedure .........................................................................................11
Your stent implant card ....................................................................................................................12
Living with renal artery disease ......................................................................................................13
Glossary ........................................................................................................................................14
Treating renal artery disease

Your doctor wants you to have a stent placed in your renal artery. This is to help treat your renal artery disease. This guide explains the procedure and what you can expect from start to finish. A glossary at the end of this guide defines common medical terms about this procedure.

You will also learn steps you can take to live a healthier life with renal artery disease.
What is renal artery disease?

Renal artery disease is caused by the narrowing of the arteries leading to one or both kidneys. This narrowing can also be called stenosis. It is usually caused by a buildup of fat or calcium deposits called plaque. Over time, this plaque can build to a total blockage of the artery. This is also called atherosclerosis.

When the kidney doesn’t receive enough blood because of a blockage in the artery, it sends a signal to the body to increase the blood pressure. This causes high blood pressure (hypertension) that can be very difficult to control. High blood pressure can increase strain on the heart by speeding the spread of atherosclerosis to other parts of the body, and it can also affect the kidney’s ability to filter the blood and remove waste.

Your kidneys are located on either side of your spine, just below your rib cage. They filter waste materials out of your blood and help keep your blood pressure in the normal range. The arteries that carry blood to your kidneys are called renal arteries.
Renal artery disease treatment options

There are four different treatment options for renal artery disease. All four treatment options focus on increasing blood flow to the kidneys. The type of treatment your doctor recommends depends on your symptoms.

1. **Medical therapy**
   For patients with mild to medium symptoms, doctors often choose medical therapy. This can include drugs, exercise, and regular checkups. Doctors also say to stop smoking. The doctor may prescribe drugs that dilate and expand the arteries, to increase blood flow to the kidneys and control high blood pressure. Regular checkups can help determine if more treatment is needed.

2. **Angioplasty**
   A procedure, angioplasty, can also treat vessel narrowing. A thin tube known as a guide catheter is inserted into the artery. A small balloon located on the tip of a catheter is moved to the site of the narrowing and inflated to reduce the blockage. The balloon is deflated and removed after the angioplasty is done. Angioplasty is less invasive than surgery, and the patient remains awake while the doctor performs the procedure.

3. **Renal artery stenting**
   During this procedure, a small balloon is inflated in the artery. The balloon has a small mesh tube called a stent wrapped around it. It expands the stent in the artery which keeps the artery open and helps prevent further narrowing.

4. **Surgery**
   For patients with severe high blood pressure or kidney failure, surgery may be needed. There are two types of surgery to treat renal artery disease. During a renal artery endarterectomy, the doctor makes an incision in the abdomen. This exposes the renal artery and the plaque inside the artery is removed. Patients who have this type of surgery are usually in the hospital for about a week. In a renal artery bypass, a healthy vein is removed from another part of your body. This vein is used to make a new path around the narrowed or blocked renal artery. Patients are also in the hospital for about a week after this surgery.
You should not have a stent placed in your renal artery if any of the following conditions are present:

- You cannot take medicines that make your blood take longer to clot (anticoagulants).
- You cannot take medicines that make your blood cells slippery and make it more difficult for your blood to clot (antiplatelets).
- You are allergic to stainless steel, chromium or nickel (components of the metal used to make the Express® SD Renal Premounted Stent System).

**Note:** It is very common for your doctor to prescribe specific medications before, during and after your stent placement. Common drugs that may be prescribed by your doctor include anticoagulants and antiplatelets. These medications are intended to help decrease the risk of forming a blood clot in your artery. Please check with your doctor to find the appropriate medication for you. The implantation of stents in blood vessels throughout the body is routinely performed to treat blockages and to attempt to prevent re-narrowing.
The placement of stents in blood vessels is done to treat blockages and to try to prevent re-narrowing.

**As with any stent procedure, there is a chance that complications may occur, including, but not limited to, the following:**

- Air bubble(s) in your artery
- Allergic reactions
- Bleeding
- Blood clot(s)
- Bruising or leakage of blood at your groin area or catheter insertion site
- Death
- Heart attack
- Infection
- Injury or damage to your artery or wall of the artery requiring emergency surgery or potential loss of the kidney
- Migration of the stent from its original placement
- Restenosis or reoccurrence of the artery narrowing around or within the stent
- Renal failure

Your doctor and the medical staff will monitor you during and after the procedure for complications. If a complication does occur, your doctor will decide if you require treatment. He or she will determine what type of treatment you need.
Benefits

The benefits of undergoing renal stent placement can be improved blood flow to the kidney through the artery being treated. If you had symptoms before surgery, they might improve or go away.
Summary of clinical data

The safety and effectiveness of the Express® SD Renal Premounted Stent System (Express SD Renal stent) was compared to percutaneous transluminal renal angioplasty (PTRA) in the RENAISSANCE study. The study included 100 patients. Patients who received an Express SD Renal stent demonstrated improved treatment results after nine months, as compared to PTRA. The results showed that the patients who received an Express SD Renal stent had rates of major adverse events similar to what has been reported for comparable patients in the published literature. The occurrence of major adverse events was 10.5% at 9 months and 20.9% at 3 years for the Express SD Renal stent. Major adverse events include death, target lesion revascularization, or significant embolic event. Safety and effectiveness remained stable through a 5 year follow-up period.
Before your procedure

Below is a typical checklist that your doctor may require you to go through before your procedure.

- Tell your doctor about any medications you are taking.
- Take all your prescription medications with you.
- Let your doctor know about any allergies you may have, especially to contrast dye or iodine, to metals (cobalt, chromium, nickel, titanium or stainless steel) or to plastics (polyurethane).
- Tell your doctor if you cannot take aspirin or blood thinning medicines, because these medications are usually prescribed before and after your procedure.
- Do not eat or drink anything after midnight on the night before your procedure.
- Follow the instructions you receive from your doctor and nurses.
- Make sure you understand the possible risks and benefits of your renal stent procedure.
- You could be given a sedative to relax you before starting your stent procedure. The sedative can make you sleepy.
During a typical renal stenting procedure

1. A small puncture is made in your groin. A needle is used to gain access to the femoral artery, where a wire is then fed through the femoral artery and advanced into the aorta or main blood vessel of the body. A catheter is then introduced over the wire into your body, and the physician advances it to the narrowed section of your renal artery. All wire and catheter movement is done using x-rays for guidance.

2. The diseased artery first needs to be enlarged to make room for the stent. To do this, the physician places a small, deflated balloon over the wire and through the catheter to the blocked area of the renal artery. When the balloon is in the correct position, it is inflated. This pushes the plaque buildup aside and reopens the artery to restore blood flow.

3. The balloon is deflated and removed, and a small metal mesh tube called a stent is advanced into the same blocked area of the artery and expanded against the artery wall.

4. After the stent is implanted, the catheter and wire are removed and the puncture site in your groin is closed. The stent remains in place and is designed to help keep the artery open and prevent future narrowing of the renal artery.

Images courtesy of Boston Scientific. Images are for illustration purposes only, and are not necessarily to scale.
After a typical renal stenting procedure

- You may feel sleepy from the sedative given to you. This will wear off over the next few hours.

- You will be taken to a unit where nurses and doctors can monitor you.

- Your heart rate, blood pressure, brain function and the entry site in your groin will be checked frequently.

- You will be asked to drink a lot of liquids to flush the contrast dye out of your system. You will have to stay in bed for several hours. You will be asked to keep your leg straight so the entry site in your groin can heal well.

- You may need a short hospital stay.

- You should alert your doctor or nurse if you experience any of these symptoms.
  - Severe dizziness, near blackout or fainting
  - Severe, unrelieved headache
  - Sudden blurriness or blindness in one eye or both eyes
  - Sudden weakness or clumsiness of a hand
  - Sudden weakness or paralysis of the face, arm or leg
  - Unexplained slurring of speech or difficulty with comprehension
  - Pain, bleeding or infection at the entry site in your groin

- You should avoid straining yourself or lifting items heavier than 5 pounds until your doctor lets you know that it is okay to do so.

- After you are discharged, be sure to call your doctor if you have any of the following symptoms:
  - Severe dizziness, near blackout or fainting
  - Severe, unrelieved headache
  - Sudden blurriness or blindness in one eye or both eyes
  - Sudden weakness or clumsiness of a hand
  - Sudden weakness or paralysis of the face, arm or leg
  - Unexplained slurring of speech or difficulty with comprehension
  - Pain, bleeding or infection at the entry site in your groin
Your stent implant card

Your stent implant card shown at right tells doctors, dentists and nurses that you have a stent implanted in your renal artery. This card also has:

- The doctor who put in your stent
- The doctor’s phone number
- The date the stent was put in
- Where the stent was placed in your renal artery
- The manufacturer’s lot number for the stent

The card gives your doctors, dentists and nurses information that is needed if you have any special diagnostic tests such as:

- MRI

There are also phone numbers on the card that your doctors can call if they have any questions. Your discharge nurse will fill in the card. If he or she does not, please call the doctor who placed the stent for this information.

Please ask your physician for a copy of the Patient Information Guide. Additionally, the Patient Information Guide for this product is available from the website. To view, download or print the Patient Information Guide, go to [www.bostonscientific.com](http://www.bostonscientific.com). You may also request a hard copy of the Patient Information Guide by calling 1.888.272.1001.
Living with renal artery disease

Treatment for renal artery disease includes controlling things that cause the disease. You cannot control some risk factors. You cannot change your age, gender, ethnic background or family history. However, you can change many of the risk factors for this disease.

Your doctor may suggest the following healthy lifestyle changes:

- Losing excess weight
- Quitting smoking
- Exercising regularly
- Controlling stress and anger
- Decreasing fat in your diet
- Limiting alcohol consumption

Reducing your risk factors can also have a positive impact on the long-term success of renal artery disease treatment. Talk to your doctor today about how to increase your chances for a healthier outcome and a more rewarding life with renal artery disease.
Glossary

Angiographic Suite
A combination x-ray room and operating room where endovascular procedures are performed.

Angioplasty
A minimally invasive treatment of the arteries, to open blocked arterial vessels.

Anticoagulant and Antiplatelet
Medicines that slow down the clotting of blood.

Artery
A blood vessel that carries oxygen-rich blood away from the heart to the rest of the body.

Atherosclerosis
A disease in which the flow of blood is restricted by plaque deposits in the arteries.

Balloon Angioplasty
Opening the blocked artery by using a balloon catheter that is inflated inside the vessel.

Balloon Catheter
A thin tube with a balloon attached to the tip that can be inflated to open blocked arteries.

Blood Vessel
Any of the veins and arteries that carry blood to and from the heart.

Catheter
A relatively long, flexible tube that can be passed through the blood vessels.

Catheterization Lab
A combination x-ray room and operating room where endovascular procedures are performed.

Contrast
X-ray dye used in diagnostic tests.

Endovascular
Relating to a procedure in which a catheter is inserted through the skin into a blood vessel for the treatment of vascular disease.

Femoral Artery
The blood vessels that supply blood to the legs.

Guide Catheter
A small, thin plastic tube used to provide access to parts of the body, such as the renal arteries. A guide catheter provides support for other devices your physician may use during your stenting procedure and helps the devices stay in the right place.

Hypertension
Abnormally high arterial blood pressure.
Glossary continued

Minimally Invasive Procedure
A minimally invasive procedure utilizes small instruments or devices to reduce the size of the insertion site and cause a smaller amount of trauma, like a puncture wound or scar. An invasive procedure requires insertion of an instrument or device into the body through skin or a body orifice for diagnosis or treatment.

MRA (Magnetic Resonance Angiography)
Uses a magnetic field and radio waves to provide pictures of blood vessels inside the body. It is a type of MRI scan.

MRI (Magnetic Resonance Imaging)
A non-invasive method of using a magnetic field and radio waves to produce detailed images of the inside of the human body.

Occlusion
Blockage of blood flow in the artery.

Peripheral
Related to areas of the body outside the heart and brain.

Plaque
An accumulation or buildup of cholesterol, fatty deposits, calcium and collagen in a vessel that leads to blockages.

Renal Arteries
The blood vessels that supply blood to the kidneys

Renal Artery Bypass
A surgical procedure used to create an alternate route for blood to flow to the kidneys around narrowed or blocked renal arteries.

Renal Artery Endarterectomy
A surgical procedure that removes atherosclerotic plaque from the walls of the renal arteries.

Restenosis
Re-narrowing of the artery after treatment.

Sedative
A type of medication that makes you relaxed and sleepy. Also called sedation.

Stenosis
A narrowing of the artery.

Stent
An expandable metal tube that supports the blood vessel wall and maintains blood flow through the opened vessel.

Vascular Closure Device
Used to close the puncture site in an artery after a minimally invasive procedure.
Non-clinical testing has demonstrated that the Express® SD Stent is MR Conditional for single and overlapping lengths up to 32 mm. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla.
- Maximum spatial gradient magnetic field of 1900 Gauss/cm (19 T/m) or less.
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the Express SD Stent is expected to produce a maximum temperature rise of less than 2.0 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 11.4 mm from the Express SD Stent when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system. The artifact obscures the device lumen.

**Recommendations**

It is recommended that patients register the conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or an equivalent organization.

### Stent Identification Information

<table>
<thead>
<tr>
<th>Stent Location</th>
<th>Product Code</th>
<th>Product Lot Number</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PLEASE CARRY YOUR CARD AT ALL TIMES.**

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Date of Implant</th>
<th>Implanting Physician’s Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Emergency Contact Number</th>
<th>Physician’s Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
For more information about indications, contraindications, warnings and instructions for the Express® SD Renal Premounted Stent System, visit www.bostonscientific.com. You can also call Boston Scientific customer service at 1.888.272.1001 to request copies of the Directions for Use (DFU).

**CAUTION:** Federal (USA) law restricts these products to sale by or on the order of a physician.