

Understanding Carotid Artery Stenting

Patient Information Guide



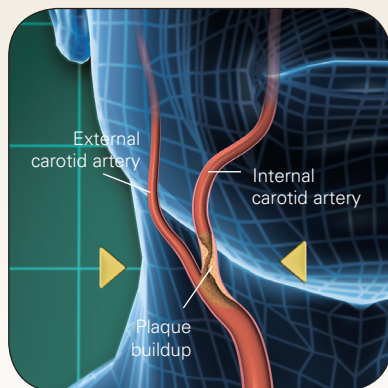
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Treating your carotid artery disease

Your physician has recommended you have a carotid artery stenting procedure to help in the treatment of your carotid artery disease. This guide explains how carotid artery stenting works, and what you can expect before, during and after the procedure. A glossary at the end of this guide defines several medical terms related to your procedure in easy-to-understand language.

You will also learn about steps you can take afterward to live a healthier life with carotid artery disease.

What is carotid artery stenting?

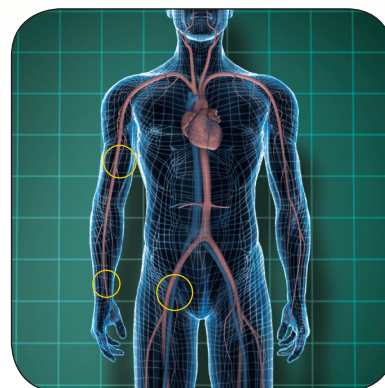


Carotid artery stenting reopens obstructed arteries that have become narrowed or blocked by a buildup of plaque known as carotid artery disease. This plaque restricts or stops blood flow to the brain, and can lead to stroke or even death. Carotid artery stenting is less invasive than surgery, and you remain awake during the procedure.

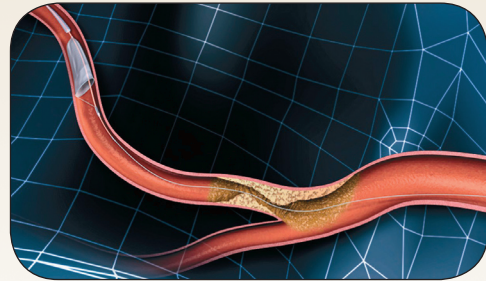
Here is what usually happens during a typical carotid artery stenting procedure.

1. A small incision is made in your groin, arm or wrist. A catheter is introduced into an artery in your body through this incision, and the physician advances it to the narrowed part of your carotid artery.

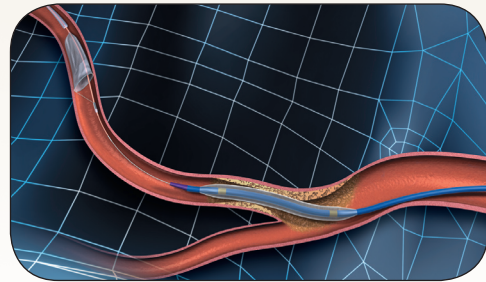
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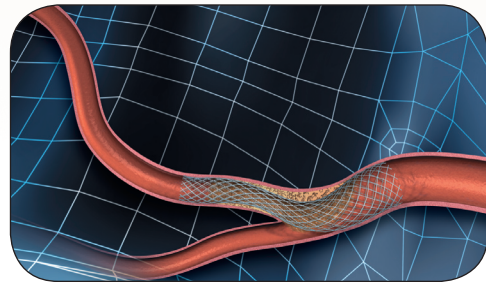
2. Next, a special filter is delivered through the catheter and placed just beyond the narrowed section of the artery. This small filter is part of a system (embolic protection system) designed to catch and remove plaque and other particles that may be released during the procedure. >>>



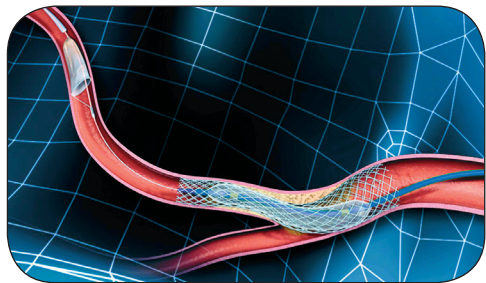
3. After the embolic protection device is in place, the artery may need to be enlarged to make room for the stent. To do this, the physician places a small, deflated balloon through the catheter to the blocked area of the carotid artery. When the balloon is in the right place, it is inflated. This pushes the plaque buildup aside and reopens the artery to restore blood flow. >>>



4. The balloon is deflated and removed. Then a small metal mesh tube called a stent is placed in the artery and is expanded to prop the artery open and allow blood flow to the brain. >>>



5. After the stent is implanted, a balloon may be inflated inside the stent to better position the stent against the artery wall; then the balloon, filter and catheter are removed. The incision in your groin, arm or wrist is closed. The stent remains in place to help prevent future narrowing of the carotid artery. >>>



More about your stent and embolic protection system

Your physician may choose to use the Boston Scientific FilterWire EZ™ Embolic Protection System with the Carotid WALLSTENT® Monorail® Endoprosthesis stent to treat your carotid artery disease. These products have received proper approval and clearance for use in the treatment of certain patients at high risk for a surgical procedure to treat their disease.

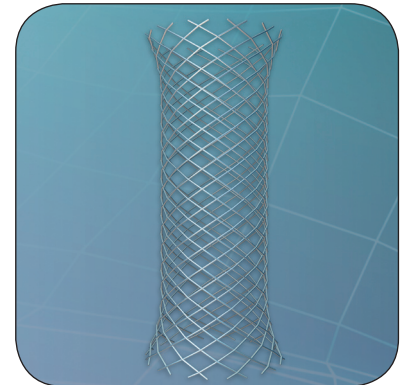


FilterWire EZ Embolic Protection System

The picture to the left shows a FilterWire EZ Embolic Protection System. It has a wire with a small filter at the end. The filter is opened during the stenting procedure and is designed to capture any particles that are dislodged and prevent them from traveling to other parts of the body.

Carotid WALLSTENT Monorail Endoprosthesis

The picture to the right shows a Carotid WALLSTENT Monorail Endoprosthesis. It is designed to prevent plaque from protruding into the artery.



Before your procedure

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

- Tell your physician about any medications you are taking.

- Take all your prescription medications with you.

- Let your physician 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 physician if you cannot take aspirin or clopidogrel, 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 physician and nurses.

- Make sure you understand the possible risks and benefits of your carotid stent procedure.

- Be aware that you may be given a sedative to relax you before starting your stent procedure. The sedative may make you sleepy.

During a typical carotid artery stenting procedure

1. You will be taken into an angiographic suite or catheterization lab and moved onto an x-ray table. In most cases, the procedure will be done through the femoral artery in your leg. To prepare for the incision, your entry site (groin, arm or wrist) will be washed, shaved and covered with a sterile sheet.
2. You will be injected with a local anesthetic to numb the area where the catheters will be inserted. After the initial sting, you may feel a brief warm sensation as the medicine is injected.
3. Your physician will insert a needle into your groin, arm or wrist to introduce the catheter into your artery.
4. Your physician will inject contrast dye into the catheter. This helps the physician see the arteries in your neck and brain on a monitor. You may feel warm or flushed for a short time.
5. Your physician will insert the embolic protection system (FilterWire EZ™ Embolic Protection System) into your carotid artery.
6. Your physician may inflate the artery at the diseased site with a balloon catheter to open the artery for easier placement of the stent.
7. Your physician will insert the stent (Carotid WALLSTENT® Monorail® Endoprosthesis), guide it to the narrowed area and open the stent to cover the diseased site.
8. Your physician may insert a balloon catheter into the stent to open it wider, then deflate the balloon and remove it. The stent will remain in place to keep the artery open.
9. Your physician will take out the embolic protection system and the catheter. Then your physician will close the small entry site in your groin, arm or wrist by applying pressure to the site or by using a vascular closure device.



After a typical carotid artery stenting procedure

- You may feel sleepy from the sedative given to you, but this should wear off in time.
- You will be taken to an observation unit for monitoring by nurses and doctors.
- Your heart rate, blood pressure, neurological status and the entry site will be checked frequently.
- You will be asked to drink lots of fluids to flush the contrast dye out of your system. You will have to stay in bed for several hours, keeping your leg, arm or wrist straight so the entry site in your groin, arm or wrist may heal well.
- You may need to stay in the hospital for one or two days.
- You should alert your doctor or nurse if you experience any of these symptoms at any time:
 - 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 at the entry site in your groin, arm or wrist
- You should avoid straining yourself or lifting items until your doctor lets you know that it is okay to do so.
- Please let the doctors and nurses know if you change your address or telephone number.

Your stent implant card

An example of your stent implant card is shown below. The card is your personal record that notifies physicians, dentists and nurses that you have a stent (Carotid WALLSTENT® Monorail® Endoprosthesis) implanted in your carotid artery. This card also identifies the physician who implanted your stent, the physician's contact information, the hospital where the procedure was performed, the date the stent was implanted, and the location where the stent was placed in your carotid artery. Other important information such as the size of the stent and the date the stent was manufactured is also included.

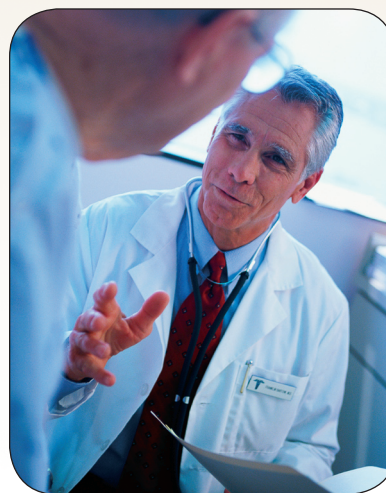
The card gives your physicians, dentists and nurses valuable information that is necessary if you should need to undergo any special diagnostic testing such as magnetic resonance imaging (MRI) or magnetic resonance angiography (MRA). There are also phone numbers on the card that your physicians can call if they have any questions. If the information within the stent implant card has not been completed prior to your discharge from the hospital, please contact the implanting physician for this information.

<p>9021277-01 Rev. A</p> <p>call (888) 272-1001 www.bostonscientific.com/carotidwallstent or For further information, please refer to Directions for Use at MRI Image Artifact has been evaluated at 1.5 Tesla only. is MRI safe at field strengths of 1.5 Tesla or less. The Carotid WALLSTENT® Monorail® Endoprosthesis</p> <p>Please carry this card at all times and show it to any medical professional who may be treating you.</p> <p>Boston Scientific</p> <p>Carotid WALLSTENT® Monorail® Endoprosthesis</p> <p>Carotid Stent</p> <p>PATIENT IMPLANT CARD</p>	<p>Patient Name _____</p> <p>Implant Date _____</p> <p>Implanting Physician _____</p> <p>Phone Number _____</p> <p>Hospital Name _____</p> <p>Hospital Address _____</p> <p>Model No. _____</p> <p>Lot No. _____</p> <p>Implant Location #1 _____</p> <p>Implant Location #2 _____</p> <p>Primary Physician _____</p> <p>Phone Number _____</p>
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Risks, benefits and contraindications

The implantation of stents in blood vessels throughout the body is routinely performed, although stent placement in the carotid arteries is a more recently developed procedure. As with any stent procedure, there is a possibility that complications may occur, including, but not limited to, the following:

- Air bubble(s) in your artery
- Allergic reactions
- Bleeding
- Blood clot(s)
- Bruising of your groin area or catheter insertion site
- Death
- Heart attack
- Infection
- Injury or damage to your artery or wall of the artery
- Minor migration of the stent from its original placement
- Restenosis or reoccurrence of the artery narrowing around or within the stent
- Stroke or transient ischemic attack (TIA)



Your physician and the medical staff will monitor you during and after the procedure for such complications. If a complication does occur, your physician will decide if you require treatment and determine what type of therapy you may need.

Risks, benefits and contraindications continued

The potential benefits of undergoing carotid stent placement include improved blood flow to the brain through the artery being treated. If you had symptoms prior to your procedure, it is possible they may resolve or improve, but there is no guarantee this will happen.

You should not undergo carotid artery stent placement 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 cobalt, chromium or nickel (components of the metal used to make the Carotid WALLSTENT® Monorail® Endoprosthesis).

Note: It is very common for your physician to prescribe specific medications before, during and after your stent placement. Common drugs that may be prescribed by your physician include anticoagulants and antiplatelets. These medications are intended to help decrease the risk of a blood clot forming in your artery. Please check with your doctor to find the appropriate medication for you.

Living with carotid artery disease

Talk to your physician today about how you can live a healthier, more rewarding life with carotid artery disease by adjusting your diet, stopping smoking, exercising and taking all your medicines regularly. Here are other steps you can take toward a healthier lifestyle:

- Work with your physician to lower your high blood pressure.
- Eat foods low in saturated fat and cholesterol.
- Lose excess pounds if you are overweight.
- Lower your blood sugar if it is high.
- If you have diabetes, see your doctor regularly and follow all instructions.
- Take medications, such as aspirin, recommended or prescribed by your physician.
- Try to reduce stress in your life.
- Attend all of your follow-up appointments.

Carotid artery disease cannot be completely eliminated, even after you have your stenting procedure. The good news is that by making positive lifestyle changes, you can significantly improve your quality of life.

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.

Carotid Artery

A key artery located in the front of the neck that carries blood from the heart to the brain.

Carotid Artery Disease

A condition that reduces the blood flow through the carotid arteries to the brain.

Carotid Endarterectomy

A surgical procedure that removes atherosclerotic plaque from the walls of the carotid arteries.

Contrast

X-ray dye used in diagnostic tests.

Embolic Protection System

A device used during the carotid artery stent procedure to capture and remove plaque and other particles that may be released during the procedure.

Endovascular

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

Guide Catheter

A small, thin plastic tube used to provide access to parts of the body, such as the carotid 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.

Minimally Invasive Procedure

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

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.

Plaque

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

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 vessel wall and maintains blood flow through the opened vessel.

Stroke

A sudden loss of brain function caused by a blockage or rupture of a blood vessel to the brain.

Transient Ischemic Attack (mini-stroke)

A sudden loss of neurological function with complete recovery, usually within 24 hours.

For more information about indications, contraindications, warnings and instructions for the FilterWire EZ™ Embolic Protection System and the Carotid WALLSTENT® Monorail® Endoprosthesis, visit www.bostonscientific.com and www.carotid.com. You can also call Boston Scientific customer service at **1.888.272.1001** to request copies of the Directions for Use.

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

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