

A Guide to Carotid Artery Stenting

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PROTÉGÉ® GPS™ Carotid Stent System
PROTÉGÉ® RX Carotid Stent System



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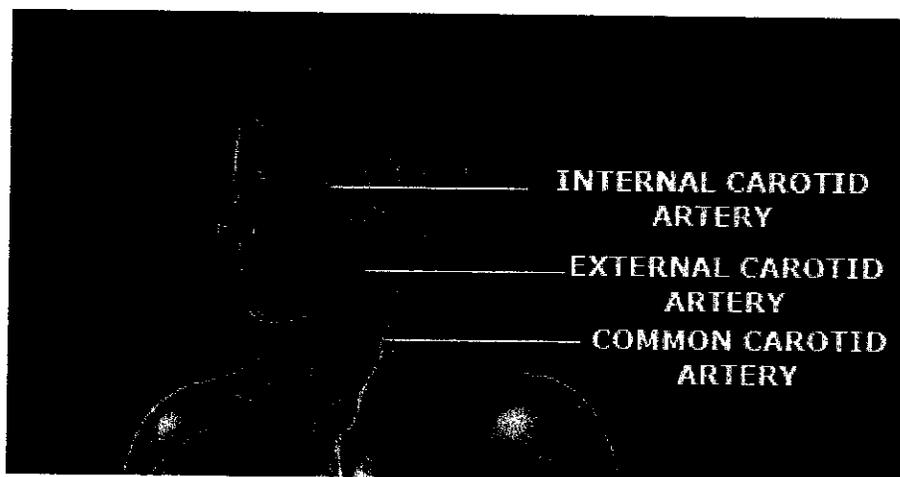
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Carotid Anatomy and Your Brain

A build-up of plaque in the walls of your arteries can restrict necessary oxygen and nutrient-rich blood to keep your brain functioning properly. The flow of blood from the carotid arteries in the neck supply the majority of this blood to the brain. The reduced blood flow through the carotid arteries is carotid artery disease. The common carotid arteries (CCA) are located on both sides of your neck, next to your windpipe. The common carotid arteries divide into two vessels – the external carotid arteries (ECA) and the internal carotid arteries (ICA). The external carotid arteries bring blood to your face. The internal carotid arteries supply blood to the large front section of your brain, which is responsible for thinking, speech, personality, and sensory and motor functions.



Carotid Artery Disease

Just like the arteries in your heart, the carotid arteries can narrow and develop blockages. This disease process is called atherosclerosis. Atherosclerosis is caused by the buildup of fat and cholesterol deposits, called plaque. Plaque causes the artery to thicken and harden, so that the flow of blood slows down. This decrease in blood flow to the brain can ultimately lead to a stroke. Atherosclerosis in the carotid arteries may cause a stroke in one of two ways.

- A stroke can be caused by plaque buildup narrowing the blood vessel so that the flow of blood to the brain is blocked.
- Pieces of plaque or a blood clot can break off and travel to a smaller artery in the brain, blocking that artery.

Risk Factors for Carotid Artery Disease

Certain factors, such as your lifestyle or family history can increase your risk of carotid artery disease. The following factors may increase your chance of developing atherosclerosis and as a result, having a stroke:

- Age
- Gender
- Race
- Family history of stroke
- Prior history of stroke
- Prior history of heart attack or heart disease
- High blood pressure
- Smoking
- Diabetes
- Obesity
- High cholesterol
- Lack of exercise

Symptoms of Carotid Artery Disease

Many people do not have any symptoms of carotid artery disease, but there are warning signs of an impending stroke. Often a stroke is preceded by a transient ischemic attack (TIA), sometimes called a mini-stroke. A TIA is a temporary episode - lasting anywhere from a few minutes to a few hours – marked by any of the following symptoms:

- Blurred or loss of vision in one or both eyes
- Weakness and/or numbness of your arm, leg or face on one side of your body
- Slurred speech or difficulty talking
- Difficulty understanding what others are saying
- Loss of coordination
- Difficulty swallowing
- Dizziness
- Confusion
- Headache

Call your doctor immediately if you have any of these symptoms. These symptoms may also be symptoms of a stroke. Immediate treatment may save your life or increase your chance of a full recovery.

If your doctor suspects that you have carotid artery disease either because you have atherosclerosis in other blood vessels in your body or if you have symptoms of the disease, your doctor may use one or more of the following tests to help diagnose your condition.

- **Health History and Physical Exam –**

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Your doctor will examine you and ask you about symptoms you may have. It is important to tell your doctor all of your symptoms, even if they were only temporary.

- **Doppler Ultrasound** –

An ultrasound, which uses sound waves to create an image, allows the doctor to see if you have blockages in your carotid arteries. This test is painless and non-invasive (performed outside the body).

- **Carotid Angiography (Carotid Angiogram, Angio or Arteriogram)** –

A catheter (small hollow tube) is used to inject contrast (dye) into the carotid arteries. X-rays are then taken to allow your doctor to see any narrowing in your carotid arteries.

- **Magnetic Resonance Imaging/Angiography (MRI/MRA)** –

An MRI uses a very strong magnet to make three-dimensional images of a part of the body. An MRI can show atherosclerosis of the carotid arteries or areas of the brain that have been damaged by a previous stroke. If your doctor wants to look at vessels, contrast (dye) will be used.

- **Computerized Tomography (CT or Cat Scan)** –

A CT scan, also called a CAT scan, uses x-rays to create three-dimensional images of a part of the body. Your doctor may inject contrast (dye) if the doctor wants to see the vessels.

Using the information gathered from these tests, your doctor will be able to better recommend the most appropriate treatment. Your doctor will explain the risks and benefits of your treatment options and answer any questions you may have.

Treatment Options

Your doctor may recommend one or more options for treating your carotid artery disease. Treatment options for carotid artery disease include lifestyle modifications, medications, surgery, and less-invasive procedures, such as placing a stent in the narrowed artery.

Lifestyle Modifications

Lifestyle changes your doctor may recommend are:

- Quitting smoking and using tobacco products
- Controlling high blood pressure and diabetes
- Having regular check-ups with your doctor
- Maintaining a diet of foods low in saturated fats and cholesterol
- Monitoring and controlling your lipids (good vs. bad cholesterol levels)
- Achieving and maintaining a desirable weight, including regular exercise
- Properly control other physical ailments, such as atrial fibrillation and heart disease

Medication

Your doctor may also prescribe blood thinner medications. Common drugs used include aspirin, Plavix[®], Coumadin[®] (also known as warfarin), or Ticlid[®]. These drugs lower your risk for blood clots. In addition, your doctor may prescribe medications to lower your blood pressure or cholesterol.

Carotid Endarterectomy (CEA)

Carotid Endarterectomy is a surgical procedure that removes the blockage in the carotid artery. An incision is made in your neck and into the carotid artery. The plaque and any diseased portion of the artery is removed and the artery is sewn back together, restoring blood flow to the brain. The procedure is usually done under general anesthesia.

Carotid Stenting (CAS)

Carotid stenting is a non-surgical, endovascular (done through or inside the blood vessels) procedure performed in a catheterization laboratory. A small puncture is made in an artery in the groin, where catheters and wires will be inserted. The procedure uses a stent (small latticed metal tube) to open partially blocked arteries and hold the plaque against the artery wall. The stent is made from nickel-titanium, a metal that is bendable, but springs back into its original shape after being bent. An embolic protection device is also used to help catch any pieces of plaque or other particles that may be loosened during the procedure. After the embolic protection device is placed beyond the narrowed area of your artery, the doctor maneuvers the stent on a catheter into the vessel. The doctor then positions the stent across the narrowed area in your carotid artery. The stent is released and stays in place permanently, holding the artery open and improving blood flow to the brain. All of the devices (except the stent) are taken out of your body at the end of the procedure.

Carotid Stent Procedure

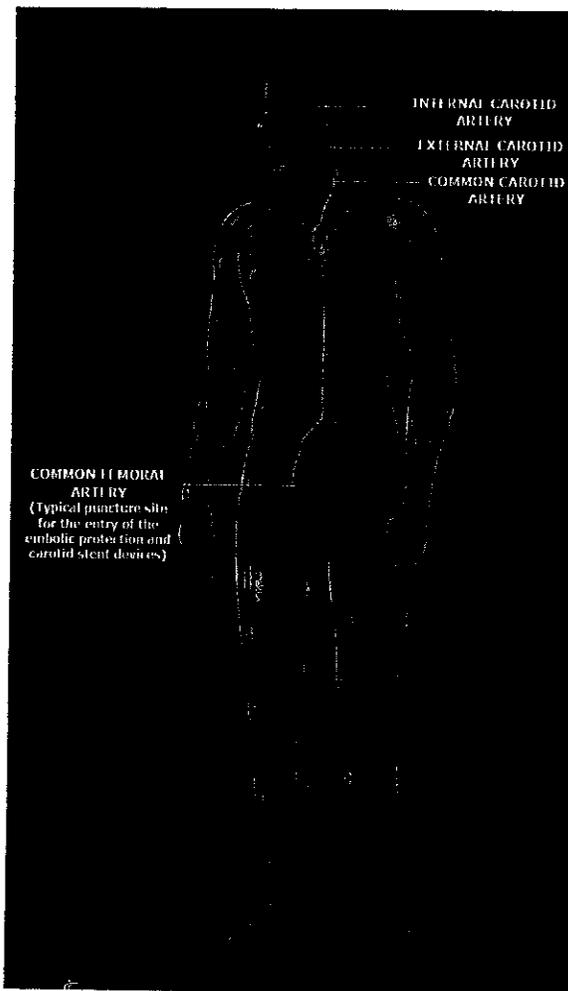
Preparing for Your Procedure

Before you go to the hospital, your doctor will give you instructions on any medication and diet changes necessary prior to your stent procedure. You should follow these instructions carefully and ask questions if you are uncertain or concerned. Make sure you:

- Take all of your prescription medications. Tell your doctor if you are taking any other medications.
- Tell your doctor about any allergies you have, especially to contrast dye or iodine, or to materials such as metals (nickel-titanium or stainless steel) or plastics (polyurethane).
- Tell your doctor if you cannot take aspirin, since aspirin and other medications are usually begun prior to a procedure and continued for several months thereafter.
- Do not eat or drink anything after midnight on the night before your procedure.

Before Your Procedure

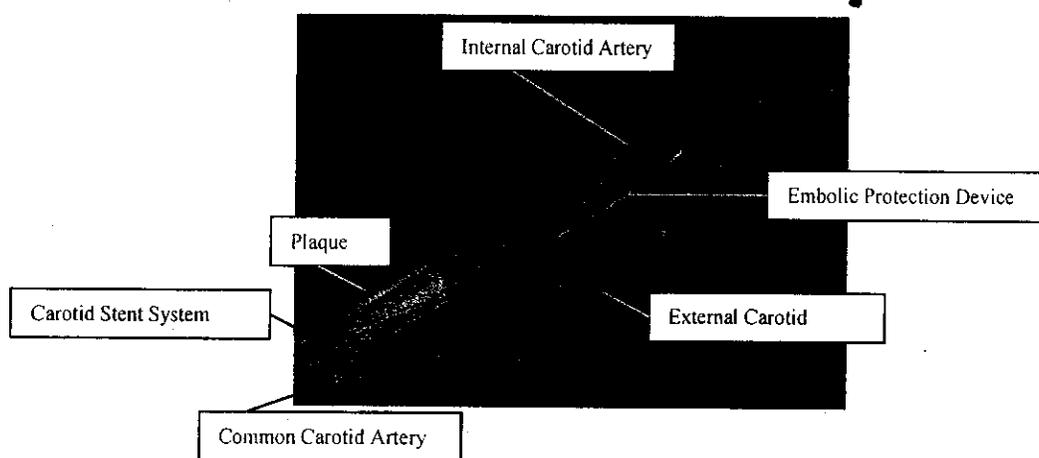
Just before your procedure, you will arrive at the hospital and be registered into the system. You will change from your street clothes into a hospital gown, have an IV started and complete any remaining testing. Any necessary medications, such as sedatives and blood thinners, may be given to you by IV or mouth.



During the Procedure

Once you enter the catheterization laboratory, many things will happen at once.

- Physicians, nurses, and technologists will place you onto the procedure table and attach monitoring equipment to you for the stenting procedure.
- You may be given additional medication to help you relax.
- During the procedure the room will be darkened and a large camera placed over you. The camera will rotate and move throughout the procedure.
- Just prior to placing any catheters into an artery in your groin, you will feel a small stinging sensation as your doctor numbs the area.



During the procedure itself, you will see, hear and feel many things:

- The doctor will use various wires and catheters to gain access to your carotid artery. These catheters will enter your body through the small incision in your groin. The catheters will travel through your body via your arteries until they reach the area to be treated. Because there are no nerve endings in your arteries, you will not be able to feel these wires and catheters moving inside you.
- As your doctor treats you, he or she will take many x-ray pictures of you using the x-ray camera and contrast dye. This contrast dye may briefly make you feel warm as it is injected.
- Once your doctor has gained access to your carotid artery, he or she will deploy a tiny filter downstream from the area that will be treated. It is possible for plaque from the diseased area to break loose and be carried downstream during the procedure. The filter will help to catch the debris and prevent it from reaching your brain. For your protection, the filter will remain open in your artery throughout the procedure.
- If the diseased area in your artery has caused the vessel to become very narrow, your doctor may use a small balloon to open it slightly. This will help your doctor reach the area where your stent will be placed. You may feel some pressure in your neck when the balloon is inflated.
- Your doctor will use a special catheter to place the stent in the diseased area of your carotid artery. This catheter contains the stent in a compressed state. Your doctor will carefully align the catheter and deploy the stent. This stent, either the Protégé® RX or

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Protégé® GPS Carotid Stent, is designed to hold plaque against the wall of your artery and prevent that plaque from breaking loose and being carried into your brain.

- After the Protégé RX or Protégé GPS stent is deployed, your doctor may use another balloon to ensure that your artery is fully opened and any plaque is pushed against the vessel wall. You may feel a small amount of pressure in your neck as the balloon is inflated. The stent will stay in place permanently.
- When your doctor is satisfied that your artery has been treated properly, he or she will close the filter and remove it and all other devices from your body.

After Your Procedure

Once your procedure is complete, you will be placed on bed rest in the hospital. The amount of time before you are allowed to stand or move freely will depend on how the incision from the catheter insertion is closed and what medication you have been given. During this time, the doctors and nurses will monitor you carefully. As always, you should let your doctor know immediately if you experience any unusual sensations such as pain, numbness, tingling, dizziness, or difficulty seeing, hearing, speaking or swallowing.

Your Recovery

Before you leave the hospital, your doctor will give you guidelines for activities, diet, and medications. Because medications will be an important part of your treatment, your doctor will prescribe drugs that you should take at home to help prevent clots from forming. You should follow your doctor's instructions very carefully and ask questions if there is anything you do not understand. It is also important to keep all follow-up appointments that are scheduled for you. Your doctor will want to follow your progress closely and will give you tests such as an ECG, ultrasound, and/or blood work. These tests are designed to detect any problems that may arise, and will help your doctor to ensure your complete recovery.

You may need to have an MRI or MRA to look at your arteries some time after your stent implant. You can have an MRI or MRA at any time after your stent is implanted; both the Protégé RX and Protégé GPS stents are MRI compatible. However, make sure you let the people operating the MRI machine know that you have a stent. Please keep your stent implant card with you and present it to the people running the MRI machine so they know what type of machine to use.

The majority of patients who go home after a successful stent implantation have no further problems. If you do experience any TIA-like symptoms, discomfort or bleeding from your puncture site, immediately contact your doctor. If your doctor is unavailable, contact your local emergency service and have them take you to the nearest hospital.

Device Descriptions

Protégé GPS Carotid Stent System

The PROTÉGÉ GPS Carotid Stent System is a self-expanding Nitinol stent system intended for permanent implantation. The self-expanding stent is made of a nickel titanium alloy (Nitinol) and comes pre-mounted on a 6 Fr, 0.014"/0.018" over-the-wire delivery system. The stent is cut from a Nitinol tube in an open lattice design, and is designed with tantalum radiopaque markers at the proximal and distal ends of the stent. Upon deployment, the stent achieves its predetermined diameter and exerts a constant, gentle outward force to establish patency.

PROTÉGÉ RX Carotid Stent System

The PROTÉGÉ RX Carotid Stent System is a self-expanding Nitinol stent system intended for permanent implantation. The self-expanding stent is made of a nickel titanium alloy (Nitinol) and comes pre-mounted on a 6 Fr, 0.014" rapid exchange delivery system. The stent is cut from a Nitinol tube in an open lattice design, and is designed with tantalum radiopaque markers at the proximal and distal ends of the stent. Upon deployment, the stent achieves its predetermined diameter and exerts a constant, gentle outward force to establish patency.

Contraindications

It is important to know whether you are eligible for carotid stenting with the PROTÉGÉ RX/ PROTÉGÉ GPS stents. There are certain circumstances where carotid stenting presents too high of a risk, and you and your doctor should discuss whether carotid stenting is right for you. Some of the reasons why carotid stenting with the PROTÉGÉ RX/ PROTÉGÉ GPS stents may not be right for you are:

- You cannot take anticoagulants (medicines that make your blood take longer to form a clot).
- You cannot take antiplatelets (medicines that make it harder for your blood cells to form a blood clot).
- You have vessels which have sharp bends that precludes safe introduction of interventional devices
- You are allergic to nickel and/or titanium.
- You have an uncorrected bleeding disorder.
- You have a vessel which is diseased at the opening of the common carotid artery.

Precautions and Warnings

There is always a chance of complications from endovascular procedures. These include:

- Complications that can occur during any endovascular procedure, such as allergic reactions, bleeding, heart attack, stroke, TIAs, or even death
- Damage to your blood vessels
- Emboli (air, blood clots, or even the stent) moving downstream from where the doctor is working
- Blood clots or problems with blood flow (restenosis) at the area where the carotid stent was placed
- Infection or bruising of your groin area where the catheter was inserted

Your Stent Implant Card

Tell any dentist or doctor who treats you for any reason that you have a stent implant in your neck, and keep your Stent Implant Card with you at all times. Your Stent Implant Card identifies the doctor who implanted your stent and how to reach him or her, the hospital where the procedure took place, and the location it was placed in your carotid artery. It also identifies important information about your stent, such as the size of the stent and the date the stent was manufactured. The card gives your doctor valuable information that is necessary if you need an MRI or MRA. There are also phone numbers on the card that your doctor can call if he or she has any questions.

Glossary of Medical Terms

Angiogram – An X-ray image of blood vessels produced with a liquid called contrast. The angiogram indicates the area of blockage in your arteries.

Angiographic Suite – The room where X-rays are taken of the blood vessels and endovascular procedures like carotid artery stenting are performed.

Angioplasty – A procedure in which a small balloon mounted on a wire is passed to the area of blockage in the artery and inflated to open the vessel. Also called PTA (Percutaneous Transluminal Angioplasty).

Artery/arteries – A blood vessel that carries oxygen-rich blood away from the heart to the entire body.

Atherosclerosis – A build-up of fatty substances that cause hardening and a narrowing of the arteries.

Balloon Catheter – A small tube with a balloon attached to the tip that is inflated to open the narrowing in arteries.

Blood Thinner - Medicines that slow the clotting of blood during before, during and/or after the endovascular procedure.

Blood Vessel – Any of the arteries or veins that carry blood to and from the heart to the rest of the body.

Blood Clots – A formation of blood into small beads that restricts blood flow.

Catheterization Lab (Cath Lab) – A room where endovascular procedures are performed.

Carotid Artery – The arteries in your neck that supply blood to the brain.

Carotid Artery Disease – A condition that restricts blood flow through the carotid arteries to the brain.

Carotid Endarterectomy (CEA) – An open surgical procedure in which the fatty substance is removed from the carotid arteries.

Catheter – A small tube that carry fluids to a vessel or allows tracking of endovascular devices like carotid stents or embolic protection devices.

Cerebrovascular – The network of blood vessels in the brain.

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Computerized Axial Tomography Scan (CT or CAT Scan) – A diagnostic test that uses X-rays to produce three-dimensional images of your arteries.

Contrast – The liquid dye used to view your blood vessel under X-ray.

Doppler Ultrasound – A non-invasive test that uses sound waves to produce images of narrowed blood vessels.

ECG – A visual image produced by sound waves (ultrasound) used to assess function of the heart.

Embollic Protection Device – An endovascular device that captures the debris released during the deployment of a balloon or carotid stent.

Embolus (plural is emboli) – A small piece of blood clot, plaque or fatty substance that breaks away during an endovascular procedure and can cause tiny blood vessels to become blocked.

General Anesthesia – Medication used to sedate you during an open surgical procedure such as Carotid Endarterectomy (CEA).

Guiding Catheter – A specific catheter (small tube) used to introduce embolic protection devices, balloon and stents into your body and remove from the carotid arteries.

Heart Attack – Tissue damage to the heart caused by a lack of oxygen from reduced blood flow to coronary arteries.

Hemorrhage – Bleeding.

Hypertension – High blood pressure.

Ischemic – Pain from restricted blood flow into the arteries.

IV (Intravenous) – Fluid injecting within a vein during an endovascular procedure.

Local Anesthesia – Medication used to numb a specific area during a minimally invasive procedure like carotid artery stenting.

Magnetic Resonance Angiogram (MRA) – An MRI that is performed with contrast dye to image blood vessels.

Magnetic Resonance Imaging (MRI) – A non-invasive test that uses a magnet to produce three-dimensional images of blood vessels.

Non-Invasive Procedure – A procedure that is performed without introduction of devices into the body.

Percutaneous Transluminal Angioplasty (PTA) – A procedure in which a small balloon mounted on a wire is passed to the area of blockage in the artery and inflated to open the vessel. Also referred to as Angioplasty.

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Plaque – A build-up of fatty substances like calcium or cholesterol that create a narrowing of the artery.

Restenosis – A re-narrowing of the artery after a procedure like carotid artery stenting.

Sedative – A medication that makes you feel relaxed and sleepy.

Stenosis – A narrowing of the artery.

Stent – A small lattice metal tube delivered through a catheter and placed at the sight of the narrowing to open a vessel and restore blood flow. The metal used in most carotid stents is nickel titanium. A stent is permanently implanted into the vessel.

Stenting – The placement of a stent.

Stroke – Tissue damage to the brain caused by lack of oxygen from reduced blood flow through the carotid arteries.

Transient Ischemic Attack (TIA) – Temporary symptoms of a stroke. This can put you at higher risk for a stroke.

Vascular Closure Device – A small device used to close the hole in a blood vessel after the carotid stenting procedure.